

ISO 12891-2:2020-04 (E)

Retrieval and analysis of surgical implants - Part 2: Analysis of retrieved surgical implants

| Contents | | Page |
|---|--|-------------|
| Foreword | | iv |
| Introduction | | v |
| 1 Scope | | 1 |
| 2 Normative references | | 1 |
| 3 Terms and definitions | | 1 |
| 4 Procedures for retrieval, handling and packaging | | 1 |
| 5 Analysis of the implant interfaces | | 2 |
| 5.1 Implant/tissue interface | | 2 |
| 5.2 Implant/implant interfaces | | 2 |
| 6 Analysis of the implant | | 2 |
| 6.1 General | | 2 |
| 6.2 Forms for recording the results of the analyses | | 3 |
| 6.3 Stage I investigation (macroscopic examination — non-destructive) | | 3 |
| 6.3.1 General | | 3 |
| 6.3.2 Identification/photography | | 3 |
| 6.3.3 Visual examination | | 3 |
| 6.3.4 Low-power optical examination | | 3 |
| 6.3.5 Further evaluation | | 3 |
| 6.4 Stage II investigation (microscopic examination — mostly non-destructive) | | 3 |
| 6.4.1 General | | 3 |
| 6.4.2 Microscopic examination | | 4 |
| 6.4.3 Fractographic examination | | 4 |
| 6.4.4 Surface topography | | 4 |
| 6.5 Stage III investigation (material investigation — mostly destructive) | | 4 |
| 6.5.1 General | | 4 |
| 6.5.2 Material composition | | 4 |
| 6.5.3 Microstructure | | 5 |
| 6.5.4 Mechanical properties | | 6 |
| 6.6 Surface-treated or coated implants | | 6 |
| 6.7 Biodegradable implants | | 6 |
| 7 Implant performance | | 7 |
| Annex A (normative) Standard forms for the analysis of retrieved surgical implants | | 8 |
| Annex B (informative) ISO documents applicable for the evaluation of materials | | 19 |
| Bibliography | | 23 |