

# ISO/TC 150 (Implants for surgery)

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The ISO/TC 150 is an interdisciplinary TC due to handling all surgical implants; thus it requires active collaboration with the IEEE and other technical committees (TCs). Nowadays, the TC is greedy for new technologies and collaboration with TCs handling additive manufacturing and biotechnology. This paper reports the current status of subcommittee (SC) 1 (Materials) and its working groups (WGs), SC 7, and WG 14, where the author is contributing as a biomaterials (not a device) researcher.

## 1. Introduction

As of August 15, 2020, the ISO/TC 150 “Implant for surgery” consists of 29 participating countries and 17 observer countries. It consists of 7 working groups (WG) directly under the TC and 6 subcommittees (SC). The WG that was added is TC 261 Joint Working Group 1 with additive manufacturing, and Prof. Kohei Murase of Osaka University has been appointed as convener of TC 150. Further, WG 8 has been restarted and WG 13 was

inactivated.

Mr. Hany Demian of the Food and Drug Administration (FDA) of the U.S. serves as the chair of the technical committee (TC). And, Mr. Klaus Zeier from Germany (DE), the secretariat country, has been appointed as the Committee Manager (CM). Among the SCs, the secretariat of SC 7 is Japan, and Dr. Ryusuke Nakaoka of the National Institute of Health Sciences serves as the CM. Moreover, Prof. Makoto Ohta of Tohoku University is the convener of WG 14, and the author is the convener of SC 1/WG 3. The author will serve as the Chair of the Japanese Working Committee and the Head of the Japanese Delegation from April 2020.

This year, the pandemic of COVID-19 made all meetings either went online meeting or canceled; the TC 150 Annual Meeting was finally canceled after changing the venue from Shenzhen (China) to Plague (Czech), but SC 1, SC 7, and WG 14 described in this paper were held online.

Table 1. Structure of ISO/TC 150

JWG 1	Joint ISO/TC 150 - ISO/TC 261 WG: Additive manufacturing in surgical implant applications
WG 7	Fundamental standards
WG 8	Breast Implants
WG 10	Use and retrieval of surgical implants
WG 12	Implant coatings
WG 14	Models of tissues for mechanical testing of implants
WG 15	Neurosurgical implants
SC 1	Materials
SC 2	Cardiovascular implants and extracorporeal systems
SC 4	Bone and joint replacements
SC 5	Osteosynthesis and spinal devices
SC 6	Active implants
SC 7	Tissue-engineered medical products

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## 2. Activities of TC 150

### 2.1 SC 1/WG 3 (Ceramics)

The Co-conveners of the SC 1/WG 3 are the author and Mr. Andy McCabe of the United Kingdom (UK). This year's conference was held online from 21:00 to 23:00 Japan time on October 28 and 29 with 31 participants from 8 countries: Brazil (3), France (1), Germany (2), Japan (4 + 4 guests), Korea (1), Switzerland (1), UK (2), and USA (7 + 8 guests). Of the six drafts toward international standards discussed this year, in three cases the author was the project leader (PL), in two cases the other Japanese delegates were the PL (the author participated as an expert), and in the remaining case, the author was deeply involved in the content as an expert. Again this year, only the author related projects were

discussed.

At last year's Lund meeting, Mr. Junji Ikeda of Kyocera Co. explained about antibacterial testing of implants as a future proposal, to which Mr. John Rose of the U.S. gave a presentation on the contents of the U.S. antibacterial task force. These contents were discussed, and it was agreed that a working group on antibacterial implants would be established directly under TC150 for discussion. Mr. Ikeda will be the convener of this working group.

The author serves as PL for "Test method for flexural strength of porous calcium salt bone void filler after preconditioning in deaerated phosphate buffered saline" and "Test method for torsional strength of porous calcium salt bone void filler after preconditioning in deaerated phosphate buffered saline". The pre-consultation has been completed for both of them, but they will go through pre-consultation again after the draft is revised.

ISO / AWI 13175-3 (PL: Mr. Ian Dunkley, USA) is a project that was to be revised according to the results of a systematic review (SR). The draft was revised to the point where it could be balloted, but due to some incomplete documentation, the ballot was postponed until it was revised. Since COVID-19 should allow for extensions of all documents, an extension of the document was agreed in principle, but in the unlikely event that an extension is not granted, the draft will be withdrawn. However, if an extension is not granted, the draft will be withdrawn, reopened, and balloted on as soon as possible.

ISO/DIS 18531 is a standard test method for bone paste, and the PL, Mr. Nobuyuki Asaoka (Hoya Technosurgical Co.), explained the revision document, but since there was not enough time to circulate it, it was decided to organize a small task force to revise it. The purpose of the TF was to vote the revised document to the Committee Draft (CD). (This case has been registered as a PWI (although it is unlikely that it will be approved to be restarted as a DIS, as too much time has passed, but depending on the direction of the revision, it may be possible).

ISO 23317 is a standard for testing the apatite forming ability of materials using simulated body fluids, but at the time of the SR, there was a strong intention to "withdraw" it from the U.S., so we decided to start its revision including withdrawal option. Dr. Masami Hashimoto (JFCC), PL, explained the revision of the scope but did not convince the opponents. As a result of the discussion, it was concluded that the IS would not be possible without major revisions,

including the main text, so it was decided to organize a small task force for the revision. In a first step, it was decided that PL would prepare a draft with amendments to address the comments made by the US during the SR and circulate it to the TF for voting so that a further TF could be organized in Japan to work on the amendments.

## 2.2 SC 1/WG 4 (Metals)

SC 1/WG 4 is convened by Mr. Andy McCabe from UK. This year, WG 4 was held on the web on Monday, October 26 and Tuesday, October 27 from 21:00 to 23:00 Japan time, with 21 participants from 8 countries: Brazil (3), France (2), Germany (1), Japan (3), Korea (1), Switzerland (1), UK (2), and USA (10 + 3 guests).

### (1) ISO/WD 5832-3, Implants for surgery -

Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

(DIS ballot in progress) The committee was informed that the SR comments from 2019-09-18 were not reflected in the revised draft and that they should be checked again and commented on. This is because the committee manager did not support the idea of stopping the DIS ballot that is currently in progress and restarting the ballot with a new revision document.

### (2) ISO/SR 5832-5, Implants for surgery - Metallic materials - Part 5: Wrought cobalt-chromium-tungsten-nickel alloy

The comments from the CD ballot were reviewed and responded to; a revised draft for the DIS ballot will be sent to ISO/CS as soon as it is available; Form 8A will be circulated with the comments and the revised draft.

It was agreed to proceed to the DIS ballot.

### (3) ISO/CD 5832-6, Implants for surgery - Metallic materials - Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy

The comments from the CD ballot were reviewed and responded to. The revised draft for the DIS ballot will be sent to ISO/CS as soon as it is available; Form 8A will be circulated with the comments and the revised draft.

It was agreed to proceed to the DIS ballot.

### (4) ISO/DIS 9584, Implants for surgery — Non-destructive testing — Radiographic examination of cast metallic surgical implants

(DIS ballot in progress) The comments on the CD ballot were confirmed.

The US expressed its displeasure that the US comments had proceeded to the DIS ballot without being discussed in the WG.

ASTM F629-20 has been issued since last year, and PL confirms that there are no substantive changes from the previously described ASTM F692-15 (which has been superseded by ASTM F692-20). Unless other points are raised by the U.S. expert, it identifies an improved supplement to 4.1, except for the amendment issues related to the ASTM copyrights present in 4.2.2 and 4.2.3. This supplement introduces more appropriate wording to promote harmonization with ASTM F629.

In view of these, it was decided that the final decision to proceed to DIS will be considered by the PL, the committee manager, and the SC 1 Chair. In order to sort out the copyright issue, the committee manager was to provide a comparison between the previous version of ISO 9584 and the current DIS. Members were to comment in detail during the DIS ballot, including consideration of any changes from the last ISO published version of the standard.

(5) ISO/AWI 15374, Implants for surgery - Requirements for production of forgings

Ms. Karen McKinlay, PL, did not attend this meeting. She reported that the first draft is scheduled to be circulated in November 2020, but the project has not met the planned target date so far.

It was also recommended that ISO 15374 be reviewed in comparison to ASTM material-specific forging standards such as F620, F621, F799, and F961, in the SR comments. Since it is important to "identify similarities, differences, and inconsistencies in content and, based on that assessment, make a judgment about the usefulness of the general forging requirements recommended in ISO 15374 and check for duplication before starting a revision/preparing a new document", it is recommended that the ASTM document It was agreed that the project should be sent back to PWI for checking, and after completion of this checking, it would be decided whether it would be best to revise ISO 15374.

(6) Duplication report: ISO 9583, Implants for surgery —Non-destructive testing — Liquid penetrant inspection of metallic surgical implant

Gary Fischmann gave an oral presentation on the ISO

9583 / ASTM 629-5 action plan template.

It was confirmed that no action is needed from the ISO side at this time, as ISO 9583 has been confirmed for the 2019 at Lund conference.

Mr. Larry Kay proposed, and the experts agreed, to submit the current action plan template to the ASTM group for review of the ASTM document under revision in order to strengthen the linkage between ISO and ASTM.

(7) Future SR

Since ISO 5832-1:2016, ASTM F138-13a, ISO 5832-7:2016 and ASTM F1058-1, which are scheduled for SR next year, will be subject to duplicate checking, duplicate checking will be carried out ahead of time if possible. All SC 1 standards cannot be checked for duplication with ASTM documents before they are submitted to SR. There was also a discussion on how to report duplication, and it was decided to discuss this further in the duplication TF. It was also reported that an equivalent procedure had not yet been established by ASTM, and that the first steps were being taken by ASTM to implement a comparison and review with the ISO standard.

2.3 SC 1/WG 5 (Plastics)

SC 1/WG 5 is convened by Mr. Ryan Siskey, US. This year, it was held online from 21:00 to 21:00 Japan time on Friday, October 30 with 22 participants from 8 countries: Brazil (3), France (2), Germany (1), Japan (3), Korea (1), UK (2), USA (9), and Switzerland (1).

Since ASTM F648 is under revision for ISO/PWI 5834-2, and the standard method for accelerated testing of UHMWPE by lipid preconditioning is under preparation, it was decided to prepare a final action plan, including duplicate confirmation, as soon as these ASTM tasks are completed.

Ms. Marie Ange Roux summarized the most important topics to be revised for ISO 14949. This matter was registered with PWI and will be handled as WG 5. Mr. Jon Moseley and Mr. Heitor Neto Luz will check for duplication with ASTM. It was also decided to disseminate information on this standard to WG 8, which has resumed its activities, and possibly circulate the document. It was also decided to disseminate information on this standard to WG 8, which has resumed its activities, and to circulate the document in some cases. It was also decided to recruit experts throughout SC 1 and to organize a project team with Ms. Marie Ange Roux

as PL and Mr. Jon Moseley and Mr. Heitor Neto Luz as members.

Mr. Hany Demian, of the US, reported on the duplication of ISO/SR 5833 and ASTM 451. General discussion was held on the harmonization of ISO and ASTM, and it was decided to continue the discussion in the task force for harmonization. It was also decided to register ISO 5833 as a PWI to resolve the duplication; PLs are Mr. Hany Demian, Mr. Boopathy Dhanapal, and Ms. Karen McKinlay.

Mr. Boopathy Dhanapal from Switzerland reviewed the list of comparative materials (Polyamide, Polyether Imide, PPHS) and reported that there is a need to standardize the instrumental materials used for implantation because there are no standards for instrumental materials. Mr. Boopathy Dhanapal, Mr. Jon Moseley, and Mr. Heitor Neto Luz will organize a project group and report on this matter at the next WG 5 meeting.

#### 2.4 SC 1 (Materials)

SC 1 is chaired by Mr. Andy McCabe from the UK and Ms. Petra Bischoff from Germany is the CM. This year's meeting was held on Thursday, November 5, from 21:00 to 23:00 Japan time, with 19 participants from 7 countries: Brazil (3), France (1), Germany (1), Japan (4), UK (2), US (7), and India (1).

This year, the resolution was to accept the recommendation of the WG mentioned above.

The contribution of Japan to SC 1 is that there are many PLs, including those for revision according to the decision of SRs. Most of the new proposals are on ceramics and came from Japan. The fact that Japanese bioceramics researchers have been leading other countries in this field shows a good sign in terms of international standardization. On the other hand, there are few new proposals, especially for metal and plastic materials. However, the WG on breast implants has resumed its activities, and the discussion on additive manufacturing of surgical implants has started in JWG 1, so we need to pay attention to future developments. In addition, Japan is about to get the conveners of the WG on antimicrobial implants in SC1, so I believe that Japan's activities are becoming more active.

#### 2.5 SC 7 (Tissue-engineered medical products)

SC 7 is chaired by Dr. Carolyn Yang, US, and Dr. Ryusuke Nakaoka, National Institute of Health Sciences, Japan, is the CM. On the other hand, the former Chair, Dr. David Kaplan,

was appointed as convener of WG 1. This year's meeting was held from 21:15 to 24:08 on October 26 (Japan time), which coincided completely with the SC 1/WG 4 meeting, so the author was unable to attend.

ISO/NP TS 24560-1 is a method for the evaluation of regenerated cartilage by MRI. Based on the results of the vote, it was decided to hold a meeting in the first half of December to prepare a CD.

The "Cell seeding method on bioceramics" presented by Dr. Motohiro Hirose of AIST at the Lund meeting in 2019 was designed to be drafted for pre-consultation by March 2021.

Regarding the two proposals from China, "Determination of residual DNA in decellularized matrices" and "Determination of type I collagen extracted from cattle by liquid chromatography-mass spectrometry," it was decided that a document addressing the comments would be voted on by NP in March 2021.

#### 2.6 WG 14 (Models of tissue for mechanical testing of implantable)

The convener is Prof. Makoto Ohta of Tohoku University and the secretary is Dr. Kiyoyuki Chinzei of AIST. The WG has held the most online meetings in TC 150 and the annual meeting was held on Friday, October 23.

WD 22926 on the Design and development of synthetic anatomical bone models for testing is in the process of being revised to start CD balloting in August 2021.

The roadmap will be reviewed, etc., in the next 6-weekly online meetings.

### 3. Summary

As mentioned above, in several fields, including bioceramics, there are many proposals from Japan, and active discussions are underway. In the TC as a whole, although the number of CM has not changed, the number of conveners has increased by one, to four. We would like to aim for more Japanese chairs (not only in the TC but also in the SC) and continue to promote Japanese proposals from new viewpoints that are scientifically more valid than those of other countries.