

Application News

No. 074

Total Organic Carbon

Cleanliness Evaluation of Orthopedic Implants Using TOC

Orthopedic implants are medical devices used to support damaged bones or even to replace missing joints. The number of surgeries for the insertion of implants is increasing because of advancements in implant products and improvement of surgery techniques. Implants must be biocompatible and especially clean to mitigate the risk of implant rejection and other health issues for the patient. Due to this, effective methods for cleaning and for the evaluation of cleanliness in the production of implants are of great importance.



Fig. 1 Artificial Knee Joint

ISO19227:2018 describes guidelines and various test methods for the evaluation of cleanliness of orthopedic implants. One parameter introduced as common practice for the evaluation of water-soluble organic contaminants, is Total Organic Carbon (TOC). While TOC measurement does not enable the identification of contamination, it can accurately define the amount of organics in total. The parameter is commonly used in cleaning validation for pharmaceutical production facilities as well.

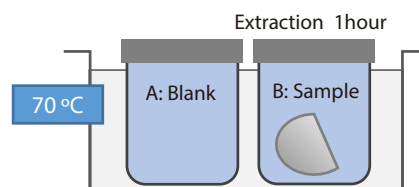
With its TOC-L series TOC analyzer, Shimadzu offers a highly suitable tool to validate the cleanliness of orthopedic implants by liquid extraction. Using the femoral component of a knee implant as shown in Fig. 1 as a test sample, organic contaminants have been purposely applied to the implant's surface. Following liquid extraction and subsequent TOC measurement, the organic contamination on the surface of the implant could be detected and evidenced quickly and with good precision.

■ Sample Preparation

Extraction liquids have been prepared according the following procedure.

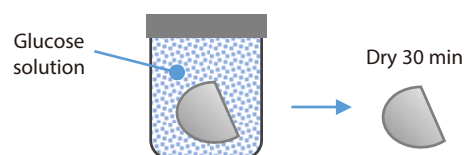
[Procedure]

1. Prepare 2 glass beakers with 250 ml pure water each. Place them in an ultrasonic bath tempered to 70 °C. One container will serve as a blank (A).
2. Place the clean implant into the other container (B). Be sure to wear clean and sterile personal equipment to avoid further contaminating the sample



3. Extract in the ultrasonic bath for 1 hour. Then remove the implant and the glass beakers and fill liquids A and B into sample vessels.
4. Conduct TOC analysis of Blank liquid A and extraction liquid B.

To simulate different types of organic contamination, in one case the implant has been submerged in a 50 mgC/L glucose solution (C). Another contaminated sample was created by shortly touching the implant with bare hands (D).



5. Repeat the procedure from 1 to 4 with the purposely contaminated implants.

The preparation of extraction liquid by this procedure is an example. Actual tests on the production site should be conducted by considering the temperature and time depending on the characterization of each product.

■ Total Organic Carbon Analyzer

TOC (Total Organic Carbon) analysis captures all carbon from organic compounds in one analysis and is therefore particularly suitable for determining contamination by organic components. Carbon content of the sample is oxidized to CO₂ and analyzed with an NDIR (non-dispersive IR) detector. The TOC value reflects the total organic contamination originating from various sources. Extraction liquids can be analyzed quickly and easily. The measurement conditions are shown in Table 1.

Table 1 Measurement Conditions

Analyzer	: TOC-LCPH
Catalyst	: High Sensitivity Catalyst
Measurement item	: TOC (=NPOC)
Calibration curve	Two 5-points calibration curves using aqueous solutions of potassium hydrogen phthalate at carbon concentrations of 0.1-0.25-0.5-0.75-1 mgC/L and 1-2.5-5-7.5-10 mgC/L
Sample	: Extraction liquid using artificial knee joint organic contamination attached

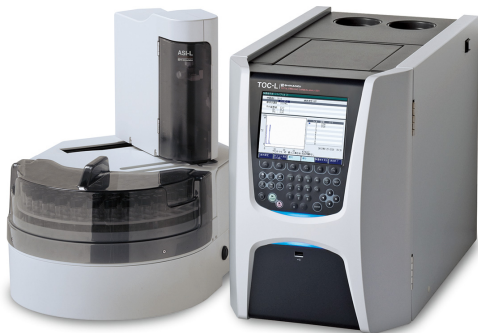


Fig. 2 Shimadzu Total Organic Carbon Analyzer; TOC-L

■ Measurement Results

The TOC results of blank, extraction liquids B are shown on the Table 2.

Table 2 Measurement Results

Sample	TOC (mgC/L)	Blank valued subtracted TOC (mgC/L)
Ultrasonic bath Blank A	0.64	-
Extraction liquid B (clean implant)	1.98	1.34
Extraction liquid C (Glucose)	3.46	2.82
Extraction liquid D (hand touch)	2.48	1.84

The results show that the even slight contamination can easily be detected and proven by TOC measurement.

This product can be used for research purposes only. This has not been approved or certified as a medical device under the Pharmaceutical and Medical Device Act of Japan.
It cannot be used for the purpose of medical examination and treatment or related procedures.

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