

Application News

No. 070

Total Organic Carbon Analysis

Quality Evaluation of Medical Devices Using TOC Solid Sample Measurement System

Many medical devices such as bone connecting materials, artificial joints, and spinal fixations devices have been developed to respond to diverse needs in medical settings. Safety is critical, as these devices are implanted directly in the human body, and high quality standards are applied to these products. Therefore, as the final quality test in the production process, an efficient method for confirming cleanliness has been required.



Because the TOC-L total organic carbon (TOC) analyzer and SSM-5000A solid sample combustion unit utilize direct combustion of solid samples, troublesome extraction work is not necessary, and measurements can be performed with a high recovery rate/sensitivity. In this study, medical devices were prepared as samples, and their cleanliness was verified by measuring the total carbon adhering to the devices by using the above-mentioned system. Products can be checked quickly and easily if any chemicals or detergents used in the production process are remained.

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■ Preparation of Samples (Medical Devices)

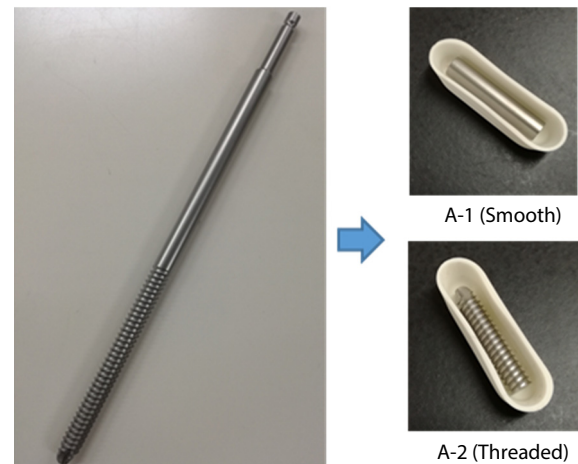


Fig. 1 Medical Device A

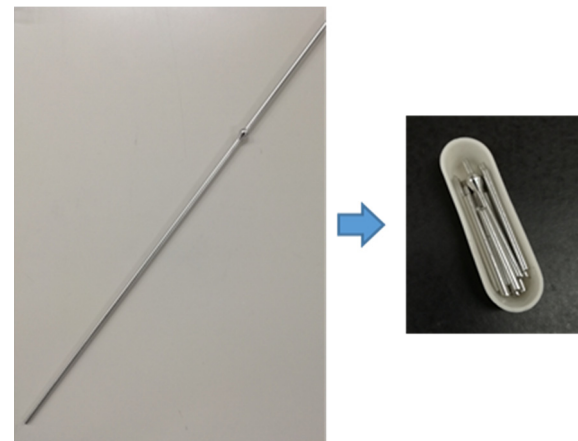


Fig. 2 Medical Device B

Medical device A was divided into a threaded part and unthreaded (smooth) part, which were cut to lengths of approximately 3 cm and placed in respective sample boats. Due to the small diameter of medical device B, the number of 3 cm cut samples placed in the sample boat (in this measurement, 10 samples) was decided corresponding to the total weight and carbon content.



Direct Combustion Method Using TOC Solid Sample Measurement System

- ✓ Does not require extraction or other pretreatment, and has a high recovery rate and sensitivity.
- ✓ Does not require chemicals.
- ✓ Quick measurement time of approximately 5 min.
- ✓ Sample boat is reusable.

■ TOC Solid Sample Measurement System

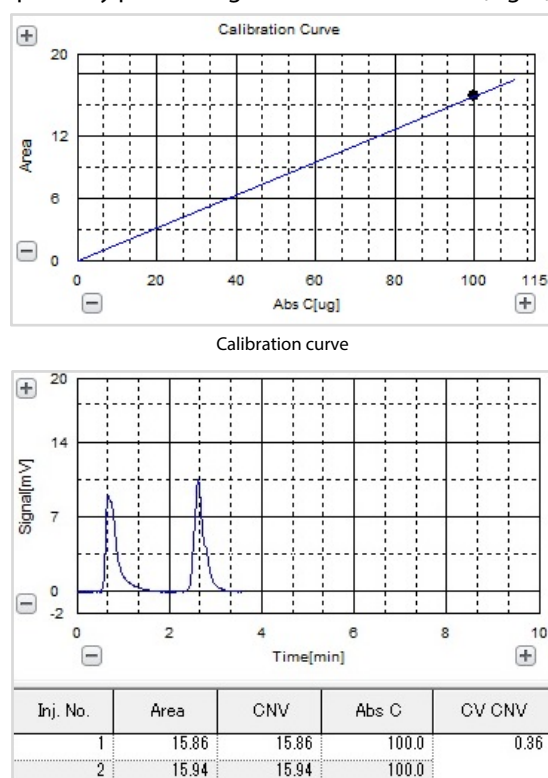
The TOC solid sample measurement system, comprising the TOC-L total organic carbon analyzer and SSM-5000A solid sample combustion unit, quantifies the organic content of a solid sample by combustion oxidation of the organic matter in the sample and detection of the formed carbon dioxide (CO₂). Since residual organic matter can be measured by direct combustion of the sample, quick and simple organic analysis without extraction or other troublesome pretreatment processes is possible. Table 1 shows the measurement conditions.

Table 1 Measurement Conditions

| | |
|---------------------|--|
| Analyzer | : TOC solid sample measurement system TOC-L _{CPH} total organic carbon analyzer + SSM-5000A solid sample combustion unit (Cell switching valve set: Specification A) |
| Cell length | : Short cell |
| SSM carrier gas | : Oxygen gas, 400 mL/min |
| TC oxidation method | : Combustion catalytic oxidation (Combustion temperature: 900 °C) |
| Measurement item | : TC (Total carbon) |
| Calibration curve | : One-point calibration curve using 0.1 % C glucose solution |

■ Preparation of Calibration Curve

100 µL of a 0.1 % C (carbon concentration: 0.1 %) glucose solution was added to heat-treated ceramic fiber in the sample boat, and the calibration curve was prepared by performing the TC measurement (Fig. 3).



Measurement of calibration curve with 100 µL of 0.1 % C glucose solution

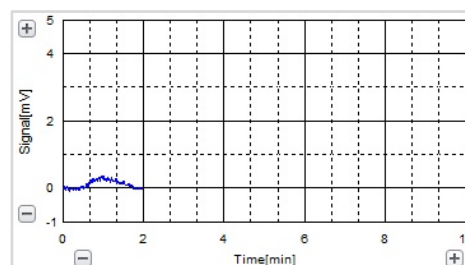
Fig. 3 Measurement Data of Calibration Curve

■ Results of Sample Measurement

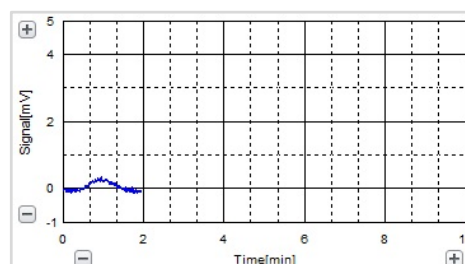
Table 2 shows the measurement results of medical device A (threaded, smooth) and medical device B, and Fig. 4 shows the peak data obtained by the measurements. As demonstrated here, the total carbon remaining in medical devices can be quantified reliably regardless of the sample shape if the TOC solid sample measurement system is used.

Table 2 Measurement Results

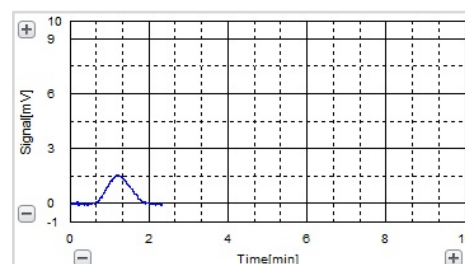
| Sample name | Total carbon (µgC) |
|-------------------------------|--------------------|
| Medical device A-1 (Smooth) | 8.252 |
| Medical device A-2 (Threaded) | 8.226 |
| Medical device B | 40.42 |



Medical device A-1 (Smooth)



Medical device A-2 (Threaded)



Medical device B

Fig. 4 Measurement Data