

DOI: 10.11910/j.issn.2791-2043.2026.1.03

Application Progress and Effectiveness of Information Traceability Systems in Loaner Instrument Management

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ABSTRACT: Driven by the large-scale expansion of healthcare services and innovations in surgical procedures, the clinical application scope of loaner instruments has expanded continuously. These instruments feature complex structures and frequent inter-institutional turnover, and their management involves multiple responsible parties, including manufacturers, distributors, central sterile supply departments (CSSDs), and surgical teams. Traditional manual management models are insufficient to meet the requirements of precision management. In the management of loaner instruments, the application of information traceability systems has gradually evolved from single-technology validation to integrated, multi-scenario implementation, accompanied by a steady increase in the volume of related research. This paper systematically reviews the application of information traceability systems in loaner instrument management in China. It highlights the advantages of these systems, including improved identification rates of loaner instruments, reduced instrument defect rates, enhanced reprocessing efficiency, greater medical staff satisfaction, and savings in medical resources. The review also summarizes the practical challenges and limiting factors currently encountered in their application, to provide a reference for medical institutions that wish to develop a more accurate, standardized, and fully traceable management system for loaner instruments.

KEY WORDS: Information traceability system; Loaner instruments; Application progress; Effect analysis

Loaner instruments are reusable medical devices provided free of charge or temporarily leased to hospitals by medical device companies or manufacturers upon hospital request. The demand for specialized surgical instruments has grown as hospital surgical services have expanded, leading to the widespread use of loaner instruments^[1]. These instruments are characterized by complexity and diversity. Many hospitals have introduced information traceability systems to manage loaner instruments, assigning them unique identification numbers to effectively ensure instrument quality^[2]. To further improve the quality of loaner instrument management in central sterile supply departments (CSSDs), this study examines the current status of information traceability systems in CSSDs, aiming to provide a reference for enhancing the quality of loaner instrument management.

As of April 12, 2026, a search of the China

National Knowledge Infrastructure (CNKI) database with the theme “Central Sterile Supply Department Information Traceability System” yielded 606 results, with records dating back to 2002. The annual publication volume on this topic from 2002 to 2026 exhibited a pattern of slow initiation, rapid mid-term growth, and a sustained high level thereafter. Specifically, the period 2002—2005 was an embryonic phase, with only 1~2 papers published per year. Rapid growth began in 2006, and the years 2012—2017 entered a high-output plateau, peaking at 50 papers in 2017. Despite minor fluctuations after 2017, the volume remained stable at a relatively high level of more than 30 papers per year from 2018 to 2025. Data for 2026 are not yet indicative of a downward trend due to the limited statistical time frame. Figure 1 illustrates the annual trend (with years and literature volumes aggregated at five-year

intervals), and Figure 2 provides details of the search formula and retrieval results (data from CNKI).

A search for the theme “Loaner Instrument Information Traceability System” from 2002 returned 119 results. From 2010 to 2026, the publication volume on this topic followed an overall trend of long-term increase with high-level fluctuations. From 2010 to 2014, the number of papers grew slowly, starting from one paper. After minor fluctuations between 2015 and 2018, the volume stabilized and then rose. Between 2019 and 2021, interest in the topic increased rapidly, reaching a peak of 16 papers in 2021. Although the volume fell back from the peak during 2022—2024, it remained at a relatively high level. Data for 2025—2026 are temporarily not indicative of a true downward trend due to the statistical time frame. Figure 3 shows the annual trend (with years and literature volumes aggregated at five-year intervals), and Figure 4 presents the search formula and retrieval details (data from CNKI).

1 Application status of information traceability systems: domestic and international

1.1 International experience with information traceability systems for loaner instruments

The application of information traceability systems in CSSD shows a notable temporal gap between domestic and international development, with devel-

oped countries, particularly those in Europe and the United States, having started earlier. Historically, the formal management of loaner instruments began in 1995, when the American Society of Healthcare Central Service Professionals (ASHCSP) and the International Association of Healthcare Central Service Material Management (IAHCSMM) jointly issued a position paper on the effective management of borrowed instruments and implants. This document serves as the starting point for formal management of borrowed medical devices. In 2004, the two organizations revised this document and issued a recommended guide for instrument pretreatment^[3], providing early normative support for loaner instrument management. A study published in 2012 found that, drawing on the Association for the Advancement of Medical Instrumentation (AAMI) standard system and multiple regional surveys, hospitals in several developed European countries had begun relevant investigations around 2005 at the level of regional exploration and technical advancement; by 2010, nearly 30% of these hospitals had adopted specialized traceability systems^[4]. In the same year, Chobin, Nancy, and colleagues further refined management methods for loaner instruments, specifying that preoperative communication with the surgeon should include the estimated surgery time, the number of required sets, the arrival time of sets, and other special circum-

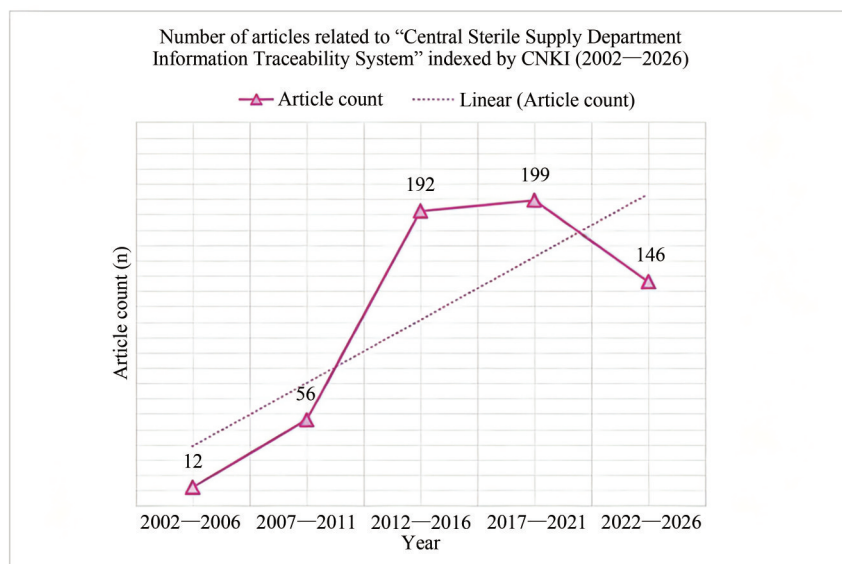


Figure 1 Articles on “Central Sterile Supply Department Information Traceability System” indexed by CNKI (2002—2026)



Figure 2 Search formula and retrieval details

stances; they also mentioned the use of computerized tracking systems for loaner instrument management^[5]. In the United States, the advancement of information traceability was driven by institutional policies. Beginning in 2007, the U.S. Food and Drug Administration (FDA) gradually implemented the Unique Device Identification (UDI) system, enabling the precise tracking of device sources through standardized identification, thereby providing a core technical foundation for more accurate management of loaner instruments^[6]. Subsequently, driven by the FDA UDI regulations and international accreditation stan-

dards such as Joint Commission International (JCI), the penetration rate in North America increased rapidly. By 2018, the coverage rate of information traceability systems in CSSDs of tertiary hospitals had reached 89%^[7].

Since 2024, the FDA has continued to strengthen its international standardization efforts while promoting a transition to electronic documentation management. These efforts have markedly improved the efficiency of loaner instrument management and enhanced international harmonization. At present, information traceability systems have been widely adopted in hospitals around the world, particularly in developed countries, where they have become a standard component of hospital infection control and quality management. A comprehensive survey of 32 hospitals in Germany found that 30 hospitals (93.75%) used information technology to manage medical sterilization instruments^[8], confirming that foreign countries, especially developed nations, have universally applied information traceability systems to the management of loaner instruments and other medical devices.

1.2 Domestic application of information traceability systems for loaner instruments in China

Although the large-scale application of information traceability systems in China has lagged behind that in developed countries, it has subsequently developed rapidly^[9]. A national survey conducted in

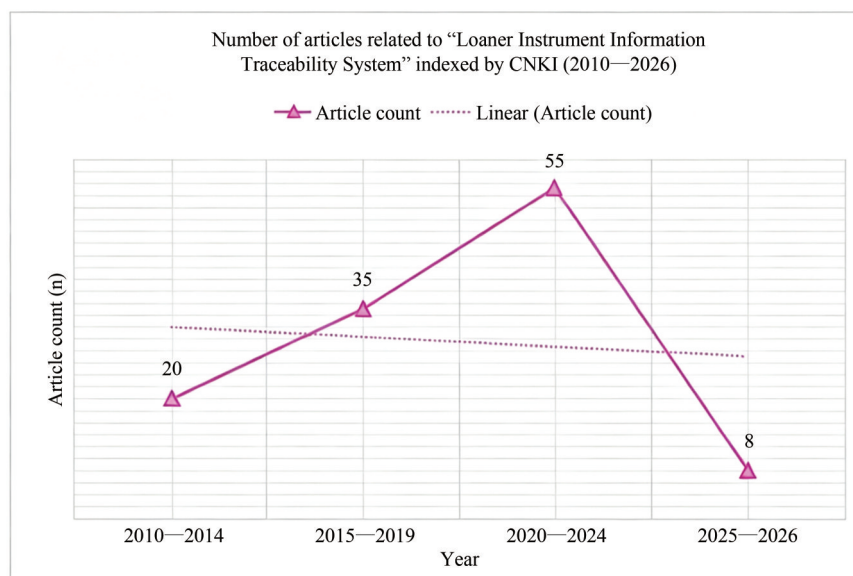


Figure 3 Articles on “Loaner Instrument Information Traceability System” indexed by CNKI (2010—2026)

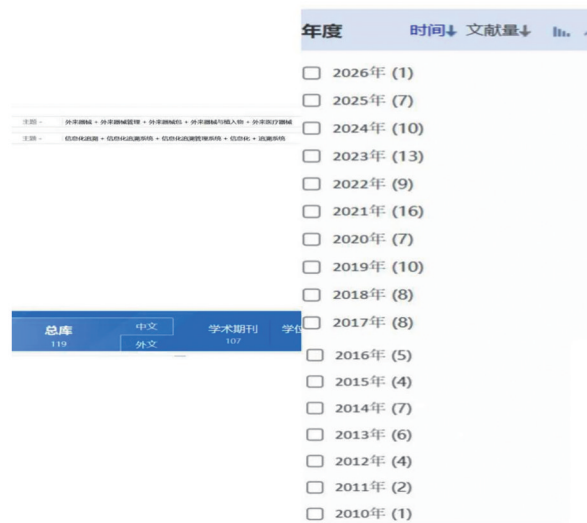


Figure 4 Search formula and retrieval details

2014 showed that only 9.6% of CSSDs in tertiary hospitals in China had established relatively complete information traceability systems^[10]. In 2016, the former National Health and Family Planning Commission of the People's Republic of China issued three mandatory health industry standards for the *Central Sterile Supply Department* (WS 310—2016), explicitly stating that “an information traceability system should be established”, which marked an important policy turning point^[11]. Driven by this policy, the penetration rate rose rapidly. A national cross-sectional study conducted by Zhang Yu et al. indicated that the deployment rate of information systems in the CSSDs of tertiary hospitals in China had risen to 91.0%, whereas the figure for secondary hospitals was only 60.2%, with unbalanced regional development^[12].

A survey study conducted in 2025, covering 3,074 hospitals across 31 provinces and municipalities in China, reported that 1,811 hospitals (approximately 59%) had implemented CSSD information traceability systems^[13]. Among these, the usage rate in tertiary and above hospitals exceeded 75%, whereas that in secondary hospitals was only about 35%, representing a substantial disparity. Of the hospitals using the system, approximately 85% had applied it to the management of loaner instruments. These findings suggest that the informatization level of CSSDs in primary hospitals in China still requires further improvement. The implementation of these systems en-

ables closed-loop management of loaner instruments, promotes continuous quality improvement, and fosters a more efficient and safer medical environment^[14]. It also plays an important role in reducing information transmission delays and information asymmetry^[15]. Currently, the construction and application of information traceability systems are increasing significantly with higher hospital tiers^[16]. With technological advances, the application scope of these systems has gradually expanded into multiple specialized fields, including precision ophthalmic instruments, gastrointestinal endoscope disinfection, and orthopedic and cardiology implants^[17-19], indicating that the system now has the capacity to meet the hygiene management requirements of most medical devices.

However, some hospitals have not yet established medical device information traceability systems, which has led to frequent instrument management issues, including inaccurate information transmission, incomplete records, and delayed processing of emergency sterilization packages. Several factors may explain this situation: some hospitals have uneven management concepts, perceive system construction costs as high, prioritize clinical services over information technology, and fail to fully recognize the importance and potential value of hospital infection control informatization. In addition, inadequate system maintenance and an inability to adapt systems to hospital-specific needs further constrain their promotion and application^[20].

The above findings indicate that, as requirements for medical quality and safety continue to increase, a growing number of secondary hospitals are gradually introducing information traceability systems to enhance hospital management and create a safer, more efficient medical environment. This has become a notable trend in the current development of CSSDs in primary hospitals. CSSDs in large tertiary hospitals should focus on developing and implementing information traceability systems that are more personalized, functionally integrated, efficient, and cost-controllable, so as to further optimize management processes and accommodate more complex clinical needs^[21].

Figure 5 illustrates the evolution of information traceability system coverage rates in CSSDs from 2005 to 2023, comparing domestic and international trends. In foreign countries (represented by developed nations), adoption began earlier: coverage rose rapidly after 2005, reached 30% in 2010, exceeded 85% in 2018, and then entered a plateau phase at approximately 90% after 2020. Domestically, a pattern of “late catching-up” is observed. Coverage was nearly zero before 2010, gradually increased after 2010 following the implementation of standards such as WS 310 and accelerated markedly after the pilot of the *Unique Device Identification System Rules* in 2018. Domestic coverage jumped from 50% in 2018 to 85% in 2023, narrowing the gap with foreign countries from 35 percentage points to 5 percentage points. The horizontal axis employs a non-equally spaced time scale, with key nodes (2010 and 2018) selected to correspond to periods of intensive policy and regulatory activity both domestically and internationally, thereby highlighting the phased impact of policy drivers on system penetration.

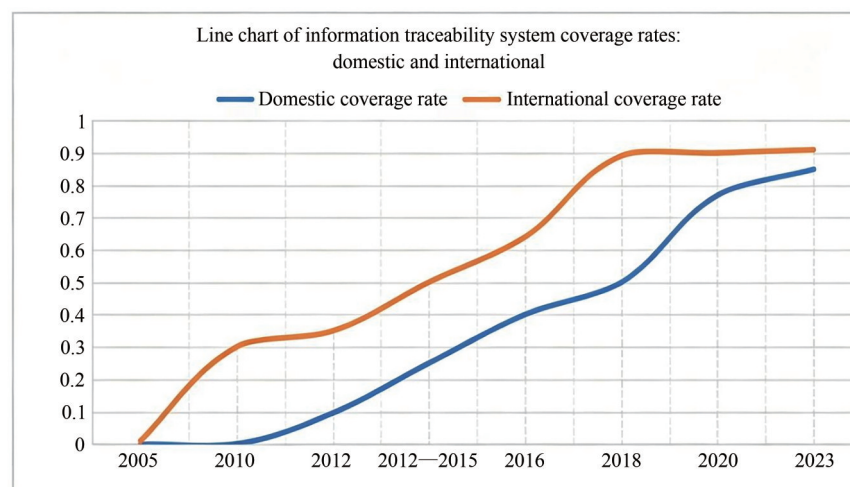
2 Application effects of information traceability systems in loaner instrument management

2.1 Advantages of information traceability systems

2.1.1 Improving loaner instrument identification rates

In the management of loaner instruments, the

primary advantage of information traceability systems lies in their ability to achieve rapid, accurate, and efficient identification and traceability. Loaner instruments are characterized by fast iteration and complex, precise structures, which impose high demands on the timeliness and accuracy of their identification and traceability. Information traceability systems provide essential support for establishing a refined and standardized management model^[22]. The study by Qiu et al.^[23] demonstrated that integrating an expanded module of the information quality traceability system into CSSD loaner instrument management, which employed both digital information visualization and container graphic identification, significantly enhanced staff efficiency and accuracy in identifying instruments. In that study, two groups were established (Group A as the control and Group B as the experimental group). The results showed that the instrument delivery error detection rate in Group A (46.32%) was significantly lower than that in Group B (100%), whereas the time required in Group A (103 S±10 S) was significantly longer than that in Group B (54.6 S±3.4 S). More importantly, information traceability systems assign a unique identifier to each loaner instrument, enabling full-process closed-loop management and real-time dynamic monitoring across medical centers. This ensures instant recording, convenient access, and ac-



Note: Foreign data were sourced from the industry survey reports of the International Association of Healthcare Central Service Material Management (IAHCSCMM, now Healthcare Sterile Processing Association, HSPA) for the period 2010–2020. Domestic data were derived from the national CSSD status survey published in the *Chinese Journal of Nursing* in 2020, as well as from recent industry survey compilations.

Figure 5 Coverage rates of information traceability systems: domestic versus international trends

curate updating of instrument information, thereby truly achieving fully controllable and traceable loaner instrument management^[24].

2.1.2 Reducing instrument defect rates

Information traceability systems not only enable efficient identification of loaner instruments but also facilitate timely detection of problems and defects during the cleaning process, thereby improving instrument cleaning qualification rates. A foreign study noted that the SPD tracking system in the United States has markedly enhanced surgical instrument quality control, offering direct international evidence that information traceability systems reduce instrument defect rates^[25]. A related study conducted at a hospital in Jiangsu Province, China, reported that the information traceability group demonstrated significantly better outcomes in instrument cleaning quality, packaging accuracy, and instrument defect rate than the conventional control group^[26]. Specifically, in the conventional control group, the instrument cleaning quality rate, disinfection accuracy rate, and packaging qualification rate were 94.71%, 94.71%, and 95.98%, respectively; the corresponding values in the experimental (information traceability) group were 99.75%, 99.78%, and 99.78%. In another retrospective study, not only were cleaning quality and instrument defect rate significantly better in the information traceability group than in the conventional group, but the accuracy rates for instrument delivery and verification were also significantly higher^[27]. These improvements not only substantially reduce the iatrogenic infection rate among hospitalized patients but also enhance the hospital's quality control capability and strengthen its regional influence.

2.1.3 Enhancing reprocessing efficiency of loaner instruments

Related research has shown that the reprocessing efficiency of loaner instruments was significantly higher in the group that used an information traceability system combined with instrument diagram technology than in the conventional treatment group. The mean total reprocessing time for loaner instruments was (148.19±4.47) minutes in the experimental

group, which was lower than that in the conventional group (180.01±6.29) minutes with a statistically significant difference ($t=56.751$, $P<0.001$)^[28]. This finding indicates that the information traceability system achieves greater work efficiency in cleaning loaner instruments. Therefore, the application of information traceability systems can shorten reprocessing time, improve reprocessing efficiency, optimize CSSD workflow, and reduce the workload of medical staff. Moreover, the use of information technology to enable full-process traceability and supervision provides solid support for hospitals in implementing refined management and ensuring medical safety, thereby contributing to improved overall quality of regional medical management.

2.1.4 Increasing medical staff satisfaction

Owing to their efficient traceability capabilities and high cleaning qualification rates, information traceability systems markedly improve the work efficiency of CSSD staff and reduce their working time. One international study reported that with the adoption of information technology, job satisfaction among CSSD staff rose from 54% to 89% over seven years, representing a 64.8% increase^[29]. Similarly, domestic studies have confirmed that after implementing information traceability systems, nursing staff satisfaction scores improved significantly compared with pre-implementation levels^[30]. Specifically, the nursing satisfaction score in the control group (84.19±4.03) was significantly lower than that in the experimental group (93.42±2.71). Furthermore, the application of these systems to loaner instrument management also contributes to higher surgeon satisfaction with surgical instruments. Data from the study by Liu et al.^[31] showed that the satisfaction scores from various departments were 71.24±8.28 in the control group and 84.36±8.06 in the traceability group. The use of information traceability systems not only enhances staff members' sense of responsibility but also significantly increases clinical departments' satisfaction with instrument cleaning quality. From a practical standpoint, the introduction of information traceability systems has led to a marked reduction in the defect rate of loaner instruments and more standard-

ized preoperative instrument processing procedures, thereby creating an efficient working environment for surgeons and nurses.

In summary, the application of information traceability modules for loaner instruments significantly improves medical staff satisfaction, which in turn effectively enhances the work motivation of CSSD personnel and clinical staff while reducing their work pressure.

2.1.5 Conserving medical resources

Since the introduction of information traceability systems, CSSDs have established an integrated “human–equipment–instrument–patient” closed-loop management model, which enables node-level tracking throughout the instrument lifecycle, facilitates real-time sharing of hospital equipment data, eliminates information silos, and significantly improves the comprehensive utilization rate of medical resources^[32]. Research indicates that after implementing an information traceability system, the utilization rate and cost-effectiveness of 391 sets of medical equipment were $(64.23 \pm 18.17)\%$ and $(52.92 \pm 15.20) \times 10^4$ yuan, respectively, both higher than pre-implementation levels, while the equipment usage fluctuation rate was $(3.71 \pm 1.15)\%$, lower than before implementation. Furthermore, after management with the information traceability system, the maintenance time and monthly maintenance cost for the same 391 sets of medical equipment were (8.81 ± 1.19) days and $(1.83 \pm 0.28) \times 10^4$ yuan, respectively, both lower than pre-implementation values^[33]. For loaner instruments, through standardized process embedding, dynamic warning, and continuous improvement mechanisms, the system can identify deviations at the earliest opportunity and trigger corrective actions, thereby significantly reducing the loss rate of medical consumables and instruments. This achieves dual savings in human and material resources and releases considerable stock medical resources for hospitals^[34].

2.2 Practical dilemmas and constraints in information traceability management of loaner instruments

Currently, information traceability systems for loaner instrument management continue to encounter multiple challenges, such as inadequate coverage,

uneven institutional implementation, and several prominent limiting factors. Loaner instruments are typically high in cost, highly specialized, subject to rapid turnover, diverse in type, and frequently moved between locations. These characteristics impose increasing professional demands on their cleaning and management, presenting significant challenges to the CSSDs primarily responsible for processing such instruments^[35]. To address the complexity of loaner instrument management, many domestic medical institutions have introduced information traceability systems to enable full-process instrument management. This has facilitated information sharing and real-time monitoring, thereby improving CSSD quality control, increasing the traceability rate of instrument information, and reducing the risk of hospital infections due to inadequate cleaning and disinfection. Nevertheless, several notable problems persist in the practical application of these systems. First, one study compared three commercially available information traceability systems and found differences in traceability time; some systems exhibited errors in information collection, low data processing efficiency, and relatively simplistic design^[36]. Second, human factors have a significant influence: staff may commit omissions or errors in data entry because of inexperience, fatigue, or lapses in attention^[37]. Third, the cost of implementation is high; some hospitals consider the expenses associated with system acquisition, ongoing maintenance, and related staff training to be burdensome^[13]. Fourth, system security still remains a concern, and data management and privacy protection mechanisms require further strengthening^[38].

3 Summary and future perspectives

Currently, information traceability systems in CSSDs have advanced from the single-technology verification stage to an integrated, multi-scenario implementation stage. In some hospitals, these systems have achieved full-process traceability of instruments from retrieval and cleaning to disinfection, sterilization, and distribution^[39]. In certain regions, cross-institutional data sharing models are being explored. For example, regional central sterile supply sharing

centers have realized instrument sharing and traceability across multiple hospitals through information systems. Not only does this model improve resource utilization efficiency but also enhances the transparency of instrument management^[40]. In recent years, information traceability systems have become deeply integrated into core CSSD operations. Most systems currently employ information technologies such as QR codes and chips, fundamentally transforming the management model of loaner instruments that was previously reliant on manual recording, information lag, and illegible handwriting. At present, information traceability systems are moving toward greater intelligence, standardization, and ecological integration. Internet of Things sensors enable real-time monitoring of equipment operating parameters, and artificial intelligence algorithms provide predictive maintenance and intelligent alerts for cleaning failures and sterilization risks. On the data front, there are efforts underway to establish regional central sterile supply information platforms and to explore cloud-based shared databases, aiming to enable cross-institutional resource scheduling and quality collaboration. In the future, it may become feasible to gradually open visualized traceability portals to patients, thereby establishing a closed-loop “instrument–surgery–patient” archive.

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