

## ORIGINAL ARTICLE OPEN ACCESS

# Closed-Incision Negative Pressure Therapy: Scoping Review and Multidisciplinary Consensus Recommendations of the Spanish Observatory of Infection in Surgery

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## ABSTRACT

Surgical site infections (SSI) and surgical site complications (SSC) significantly impact surgery outcomes, increasing hospital stays and mortality rates, and negatively affecting patients' quality of life. Closed-incision negative pressure therapy (ciNPT) emerged as a prophylactic strategy to reduce these complications. However, its applicability across different surgical procedures remains unclear. A scoping review was conducted to synthesise the available evidence on the use of ciNPT in different surgical contexts. A multidisciplinary panel of experts from different surgical specialties was assembled to identify patient risk factors for SSCs specific to each modality. Surgical procedures were categorised based on anticipated SSC rates and the impact of SSI. A decision diagram was finally developed, providing tailored recommendations for ciNPT use according to individual surgical circumstances. The findings of the review indicate that ciNPT effectively reduces SSI and SSC in most surgical procedures. Key patient-related factors influencing outcomes, such as age, obesity, and malnutrition, were outlined. Additionally, a specialty-based list of surgical procedures was compiled, specifying whether ciNPT is recommended, not recommended, or conditionally recommended based on specific criteria. This study underscores the benefits of ciNPT and provides a comprehensive guide to its application across several surgical specialties, aiming to optimise patient management and inform clinical practise.

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## 1 | Introduction

Surgical site infections (SSIs) are one of the most commonly reported hospital-acquired infections, constituting up to 19.6% of all of them in Europe during 2011–2012 [1–3]. The SSI rate varies according to the surgery type, ranging from 0.6% in knee replacement surgery to 9.5% in open colon surgery [2].

SSIs are associated with longer postoperative hospital stays, additional surgical procedures, and treatment in intensive care units, resulting in a great economic burden, as well as with a negative impact on patients' quality of life and increased mortality [4]. In addition to SSIs, other surgical site complications (SSCs) such as seroma, haematoma, incision dehiscence, and skin necrosis frequently occur in surgical wounds and are associated with increased healthcare utilisation and costs and with significant morbidity and mortality [5, 6].

Prevention of both SSIs and other SSCs can be achieved through several pre-, intra-, and postoperative strategies [7, 8]. These include basic care strategies and the use of different dressings, among others. One of the existing options relies on the prophylactic use of negative pressure wound therapy on closed incisional wounds (ciNPT), which refers to any type of negative pressure wound therapy using foam-based dressings over closed incisions [9]. A previous meta-analysis has shown that ciNPT is effective in reducing SSCs, including SSIs in different types of surgery [10]. However, the indications for care practise at that moment were unclear [10, 11].

In this context, the Spanish Observatory of Infection in Surgery (OIC) published in 2023 a consensus document with recommendations for the prevention of SSIs in different surgical specialties, with the development of several prevention bundles (PRIQ-O) [12]. Among the preventive measures included in the PRIQ-O packages was ciNPT, for which general recommendations were issued in a period prior to the emergence of new scientific evidence recently published in a meta-analysis and trial sequential analysis [13]. It was therefore considered appropriate to review and expand the recommendations in this regard.

Considering the above, the goal of this study was to identify risk factors associated with the patient, the surgical site, and the surgical procedure to serve as the bases to elaborate recommendations on the use of ciNPT for general and specific surgical specialties.

## 2 | Methods

This article is the outcome of a literature review and a series of focus meetings on ciNPT use organised by the OIC with a multidisciplinary panel of experts. In an initial session, the panel shared information about the ciNPT application across various surgical settings and outlined the manuscript's structure. In a concluding hybrid meeting (both online and in person), the experts finalised recommendations, determined the manuscript structure, and identified the key concepts to be addressed.

## 2.1 | Literature Review

### 2.1.1 | Literature Search

A literature search was conducted in January 2024 to identify the most relevant studies in the field published in the last 10 years (January 2013 to December 2023). A clinical librarian was consulted to assist in the online search, which was conducted in Pubmed, MEDLINE, Cochrane, and Scopus databases using the following terms: (Negative-Pressure Wound Therapy OR NPWT OR ciNPT OR negative pressure OR vacuum assisted closure OR VAC OR TNP OR surgical incision management OR closed incision management OR incisional management system) AND (surgical site complication OR surgical site occurrence OR surgical site event OR surgical site infection OR surgical wound infection OR surgical wound dehiscence OR seroma OR hematoma OR necrosis OR surgical wound OR surgical incision) AND (meta-analysis OR systematic review).

This study follows the guidance framework for conducting scoping reviews developed by the Joanna Briggs Institute [14] and is reported in line with the Preferred Reporting Items for Systematic Review and Meta-Analysis extension for scoping reviews (PRISMA-ScR) [15]. A predefined search strategy was used across Pubmed, Scopus, and Cochrane databases, with additional relevant articles identified through a manual review of reference lists from included studies. All retrieved records underwent double screening for eligibility.

### 2.1.2 | Eligibility Criteria and Data Extraction

Studies focusing on negative pressure therapy for open wounds were excluded from this review. Meta-analyses and systematic reviews of both randomised control trials (RCTs) and observational studies (cohort and case-control studies) assessing the effects of ciNPT in surgical patients of different specialties were included. To avoid influencing the results of this study, publications of national or international consensus statements on the use of the therapy were excluded. Articles written in English or Spanish containing multiple meta-analyses were included, and each respective meta-analysis was independently assessed for inclusion. Two investigators individually conducted the search and data extraction. Discrepancies were resolved by consensus. For dissemination among the panellists, the most relevant meta-analyses in each speciality were chosen based on the number of studies and patients included and the quality of the methodology applied.

### 2.1.3 | Definitions

SSCs refer to a range of adverse events occurring at or near the site of a surgical incision and include the terms defined in Table S1. The Centers for Disease Control (CDC) definitions for SSI were used [16]. SSIs are defined as infections occurring within 30 days after the operative procedure involving skin or subcutaneous tissue (superficial SSIs), deep soft tissues (deep incisional SSIs), or any part of the anatomy other than the incision open or manipulated during the procedure (organ/space SSIs) [16].

## 2.2 | Focus Meeting

### 2.2.1 | Multidisciplinary Consensus Meeting

Using a modified consensus process described below, the panellists agreed on which patient risk factors and closed surgical incisions presented the highest risk of SSIs and created an algorithm for the use of ciNPT.

The meeting was held over a day and a half in January 2024 and was divided into the following sections: (1) presentation of the consensus methodology; (2) presentations by each panellist reporting on their experience with ciNPT and a review of the available ciNPT-focused literature from each specialty; (3) discussion of the results of the literature search and elaboration of a list of risk factors associated with the development of SSI. Risk factors for SSCs related to the type of surgery, to the surgical incision, and those related to the patient were identified and categorised; (4) open discussion on the appropriate use of ciNPT and how the indications for ciNPT could be reflected in a comprehensible way for clinicians.

The working sessions were digitally audio- and video-recorded to ensure that all points of view were captured and could be adequately reviewed.

The consensus recommendations were reached unanimously and were based on the evidence found in the literature and the experience of the panellists. To standardise the criteria, the authors categorised surgical procedures based on the anticipated surgical site complication rates and the impact of surgical site infections, utilising criteria established in the literature. The expected surgical site complication rates for each intervention were derived from data reported in the Medicare database outlined in [6]. This registry was chosen due to its extensive patient population. Alternatives, such as the Spanish EPINE Study, were considered; however, it was deemed unsuitable for this study because it reports only prevalence rates and focuses exclusively on surgical site infection rather than addressing the entire spectrum of wound complications [17].

The leading author drafted the manuscript that was critically reviewed by all panellists, who agreed on the final version of the manuscript.

### 2.3 | Selection of Panellists

The panel was composed of 10 surgeons from different surgical specialties and from different regions of Spain, recruited by the OIC considering their experience in surgical infection and whether they had previously published studies on ciNPT after a literature search limited to Spanish authors. The panellists belonged to five Spanish Scientific Societies (Spanish Association of Surgeons, Spanish Society of Angiology and Vascular Surgery, Spanish Society of Cardiovascular and Endovascular Surgery, Spanish Society of Aesthetic, Reconstructive and Plastic Surgery, and the Spanish Society of Orthopaedic Surgery and Traumatology) and also included the subspecialties of abdominal wall surgery, endocrine and head and neck surgery, bariatric surgery, hepatobiliopancreatic surgery, and colorectal surgery.

## 2.4 | Ethics Statement

As the data used in the review are publicly available, and no patients participated in the study, patient consent was not required for publication.

## 3 | Results

### 3.1 | Literature Search

A total of 288 publications were detected and analysed by title and abstract. After removing duplicates and ineligible articles, the full texts of 87 studies were reviewed and included in the study. Most of the published meta-analyses evaluated studies of orthopaedic surgery (21.8%), followed by meta-analyses including articles from various specialties (19.5%), abdominal surgery (11.5%), and caesarean sections (10.3%) (Table 1).

### 3.2 | Main Results of Systematic Reviews and Meta-Analyses

The meta-analyses reviewed showed great heterogeneity, with some having SSIs alone as the primary outcome and others a composite of SSCs. In some cases, other secondary outcomes such as wound dehiscence, re-operation, seroma, haematoma, skin necrosis, length of hospital stay, readmission, and mortality were analysed separately.

On the other hand, most systematic reviews were based on randomised or observational clinical studies involving patients at “high risk of SSCs or SSIs”, although there was no unanimity on the definition of this high risk.

Overall, the systematic reviews and meta-analyses assessed in this review, especially the more recent meta-analyses, indicate that the use of incisional negative pressure wound therapy (ciNPT) reduces the incidence of surgical site infections (SSIs); although the evidence supporting a reduction in surgical site complications (SSCs) is less robust (Table 1).

Of the total of 19 reviews in orthopaedic surgery [18–35], 18 found a decrease in SSIs with the use of ciNPT, while 8 also found a decrease in SSCs. In this surgery type, 9 studies analysed hip or knee arthroplasty and 4 analysed spinal surgery.

From the 17 meta-analyses analysing several surgical specialties together [9–11, 13, 36–48], 15 evaluated SSI as the primary outcome. Of these, 14 reported a lower SSI with the use of ciNPT. In addition, 8 studies analysed SSCs, with 7 of these studies finding a positive impact of ciNPT on these events.

In the 10 studies evaluating the use of ciNPT in open abdominal surgery [49–58], 6 of them showed that the use of ciNPT reduced SSIs; however, 2 studies presented negative results. Regarding SSC, only one study reported lower SSCs with the use of ciNPT, while in 3 studies the results were negative.

All 9 meta-analyses of caesarean sections [59–67] showed a decrease in SSIs with the use of ciNPT, while one of four studies

**TABLE 1** | Systematic reviews and/or meta-analyses according to the type of surgery and main findings regarding SSIs and SSCs.

Specialty	N (%)	References	Outcomes		
			Lower SSIs	Lower SSCs	No benefit
Orthopaedic surgery	19 (21.8)	[18–35]	Lower SSIs reported in 18 studies	Lower SSCs reported in 8 studies	
Multi-specialties	17 (19.5)	[9–11, 13, 36–48]	Lower SSIs observed in 14 out 15 studies	Lower SSCs observed in 7 out of 8 studies	
Open abdominal surgery	10 (11.5)	[49–58]	Lower SSIs in 6 studies	Lower SSC in one study	Negative effect on SSIs and SSCs in 2 and 3 studies, respectively
Caesarean section	9 (10.3)	[59–67]	Lower SSIs in all studies	Lower SSCs in 1 out of 4 studies	
Inguinal vascular surgery	8 (9.2)	[68–75]	Lower SSIs in all studies		No positive effect on SSCs in 2 studies
Colorectal surgery	5 (5.7)	[76–80]	Lower SSIs in all studies	Lower SSCs in 4 studies	
Abdominal hernia surgery	5 (5.7)	[81–85]	Lower SSIs in all studies	Lower SSCs in all studies	
Plastic & Reconstructive surgery	4 (4.6)	[86–89]	Lower SSI in 1 study	Lower SSCs in 3 studies	No benefit in SSIs and SSCs reported in 2 and 1 studies, respectively
Breast surgery	4 (4.6)	[90–93]	Lower SSIs in 1 study	Lower SSCs in all studies	
Oncological surgery	2 (2.3)	[94, 95]	Lower SSIs in all studies	Lower SSCs in all studies	
Hepato-bilio-pancreatic surgery	2 (2.3)	[96, 97]			No benefit in SSIs or SSCs reported in all studies
Sternotomy in cardiac surgery	1 (1.1)	[98]	Lower SSIs in this 1 study	SSCs not reported	
Head & Neck surgery	1 (1.1)	[99]	SSIs not reported	Lower SSCs in this 1 study	
Total	87 (100)				

assessing SSCs showed a reduction in complications. However, it is worth noting that most of these were performed in patients with high body mass index (BMI).

The 8 meta-analyses conducted in vascular groin surgery [68–75] showed a decrease in SSI with the use of ciNPT devices. However, the 2 studies that analysed SSCs did not find the same positive effect.

All 5 meta-analyses in colorectal surgery show a decrease in SSIs and 4 of them also observed a reduction in SSCs [76–80]. Similarly, ciNPT reduced SSIs and SSCs in all 5 studies of abdominal incisional hernia surgery [81–85].

In breast surgery, all 4 studies showed a decrease in SSCs, while only 1 study reported lower SSIs [86–89]. However, the 4 studies in reconstructive surgery [90–93], which have been performed on heterogeneous types of procedures, often with flaps or skin grafts, show a disparity of results; 3 meta-analyses reported a decrease in SSCs, which was not confirmed in another study, while for SSIs, 1 study showed a positive effect and 2 found no beneficial effect when using ciNPT.

Regarding the two meta-analyses performed in oncological surgery [94, 95], all reported lower SSIs and SSCs in patients with ciNPT. In contrast, the two meta-analyses in hepato-bilio-pancreatic surgery showed no decrease in SSIs or SSCs [96, 97].

The only systematic review on the use of ciNPT in sternotomy showed a decrease in SSIs in this type of surgery [98]; while the one on neck surgery targeted SSCs, reporting a positive effect [99].

### 3.3 | Risk Factors for Surgical Site Complications

Based on the information obtained in the selected studies, general risk factors for SSCs related to patient profile, surgical incision, and type of surgical procedure were identified (Table 2). Additional risk factors associated with specific types of surgery were also identified (Table 3).

#### 3.3.1 | Patient-Associated Risk Factors

Overall, older age has been identified as a risk factor for SSIs in different types of surgery [100, 101], although not all studies report an advanced age as a risk factor [102]. In addition, male sex has been identified as an independent risk factor for SSIs in some types of surgery such as abdominal (odds ratio [OR]: 2.6), dermatologic (relative risk [RR]: 1.51 and OR: 5.46), and foot and ankle surgery (OR: 1.34) [100, 102, 103]. In contrast, a meta-analysis of studies performing vascular surgery identified female sex as a risk factor (OR: 1.41) [104].

On the other hand, patients' clinical characteristics can increase the risk of SSIs appearance.

Diabetes is one of the most frequent risk factors for SSIs found in the literature (RR: 1.48–1.68; OR: 1.80–3.00) [100, 102, 103, 105, 106], as well as a poor general status assessed

using the American Society of Anesthesiologists classification (ASA  $\geq$  3) (OR: 1.51–2.58) [100, 101, 105].

Obesity (BMI  $\geq$  30) has been reported as a risk factor in different types of surgery (OR: 1.63–7.6) [100, 101, 104, 106]. In this context, malnutrition (BMI  $<$  20 kg/m<sup>2</sup>) was also identified as a risk factor of SSIs in patients with head and neck cancer (OR: 2.64) [105].

Active smoking is also a common risk factor of SSIs in patients undergoing surgery (OR: 1.32–1.79) [100, 101, 103, 106]. However, a meta-analysis of observational studies including patients with skin surgery showed that smoking did not affect the risk of wound infection [102]. In addition, alcohol consumption was identified as a significant risk factor for postoperative SSIs (OR: 1.57) [101].

The presence of different conditions prior to the intervention such as hypertension, chronic obstructive pulmonary disease (OR 1.42), chronic kidney disease (OR 2.13), or heart disease (OR: 2.97) has been identified as risk factors for SSIs [101, 103, 104]. Immunocompromised patients were also at higher risk of SSIs (RR: 2.11) [102]. In this regard, open fractures were considered a risk factor in ankle surgery (OR: 4.87) [101]. In contrast, the presence and type of neoplasms were not considered a risk factor in large series of patients who underwent skin surgery [102].

Regarding treatments received, chemotherapy was reported to be a risk factor of SSIs (OR: 2.36) [100, 105], while no association with anti-platelet medication or anti-coagulant was observed [102].

The Charlson Comorbidity Index (CCI) [107], which quantifies a patient's burden of comorbidities, has been shown to be a critical factor influencing the occurrence and severity of SSCs [6]. In an extensive study investigating the incidence, impact, and cost of SSCs in patients undergoing open surgical procedures, Hou et al. highlighted how comorbidities, measured by the CCI, significantly influenced SSC rates, healthcare utilisation, and outcomes across various surgical categories. Higher CCI scores were strongly associated with elevated rates of both overall and non-infectious SSCs [6]. In this study, conditions such as peripheral vascular disease, diabetes, and obesity emerged as significant contributors to heightened SSC risks, especially in complex surgical procedures. Among Medicare patients, those without comorbidities (CCI = 0) experienced an overall SSC rate of 2.32% in cardiac surgeries, whereas patients with severe comorbidities (CCI  $\geq$  5) faced rates as high as 10.45%. This pattern was consistent across various surgical categories, with the highest SSC rates observed in skin, subcutaneous tissue, and breast surgeries. Furthermore, emergency and urgent surgeries, as well as orthopaedic and skin-related procedures, demonstrated the greatest vulnerability to SSCs among patients with high CCI scores.

#### 3.3.2 | Wound-Associated Risk Factors

Regarding those risk factors associated with the surgical wound, the most commonly identified in the literature were a contaminated (OR: 4.63) or infected incision [100, 101], a long operative

TABLE 2 | General risk factors associated with the patient profile, wound, and surgical procedure.

Risk factors		Patient related		Wound related		Intervention related	
	Moderate risk	High risk	Location	Moderate risk	High risk		High risk
Age	≥ 70 years	≥ 80 years		Risk areas according to wound location		Emergency caesarean section	
Diabetes	HbA1c > 7%	HbA1c ≥ 7% + target organ damage	Intervention	Reintervention, emergency, intervention time, wide undermining, wound length	Early reintervention, emergency surgery, unanticipated long intervention time	Combined surgery (e.g., thoraco-abdominal)	
Obesity	Class I (BMI ≥ 30–34.9)	Class II (BMI ≥ 35)	Infection	Long-distance active infection	Local active infection	Inguinal lymphadenectomy	
Smoking status	Active		CDC grades	I–II	III–IV	Intraoperative transfusion	
Hypoalbuminemia	< 35 g/L	< 25 g/L				Blood loss > 500 mL	
Malnutrition	BMI < 20	BMI ≤ 16					
ASA	> 3	> 4					
Comorbidities	Chronic kidney failure (GFR > 30 mL/min/1.73m <sup>2</sup> )	Chronic kidney failure (GFR < 30 mL/min/1.73m <sup>2</sup> ), collagenopathy					
Treatment/therapy	Chemotherapy, previous radiotherapy in the intervention area, immunosuppression (corticoids, cyclosporine), biological treatment, immunotherapy, anticoagulants	Dialysis, transplant, active chemotherapy, anti-angiogenic					

Abbreviations: ASA: American Society of Anesthesiologists; BMI: body mass index; CDC: Center for Disease Control and Prevention; GFR: glomerular filtration rate.

**TABLE 3** | Risk factors associated with the patient profile, wound, and surgical procedure in different types of surgery.

Types of surgery	Risk factors		
	Patient	Wound	Intervention
General, abdominal wall, and colorectal surgery			Ostomy and ostomy closure, open-abdomen closure, complex abdominal wall techniques (abdominal component separation), transplant surgery, HIPEC
Reconstructive, plastic, and breast surgery			Breast reduction, breast implant reconstruction, free flap donor site, postbariatric surgery (abdominoplasty and cruroplasty)
Cardiac, vascular, orthopaedic, and traumatological surgery	<p><i>Vascular surgery</i></p> <p>Critical ischaemia, gangrene, infection proximal to the limb</p> <p><i>Cardiothoracic surgery</i></p> <p>Chronic obstructive pulmonary disease (high risk)</p>	Oedema/poor vascularization	<p><i>Vascular surgery</i></p> <p>Implant through the femoral artery (inguinal access), limb damage control surgery</p> <p><i>Cardiothoracic surgery</i></p> <p>Sternotomy + double internal mammary artery extraction</p> <p>Heart transplant</p> <p>Mechanical assistance device</p> <p><i>Traumatological surgery</i></p> <p>Polytraumatised patient</p> <p>Revision of hip/knee replacement, osteosynthesis failure surgery</p>

Abbreviation: HIPEC: hyperthermic intraperitoneal chemotherapy.

time (OR: 1.42–1.86) [100, 105, 108], an urgent or emergency surgery (OR: 2.12) [100, 104], and an early or unplanned reoperation (OR: 4.50) [104].

### 3.3.3 | Procedure-Associated Risk Factors

The main risk factors of SSIs associated with the surgical procedure are blood loss (OR: 2.04) [100] or transfusion (OR: 1.13–2.29) [104–106] and perioperative infection (OR: 2.46) [100, 108].

## 3.4 | Panel Recommendations

After the panellists reached a consensus on the categorisation of risk factors to define indications for the use of ciNPT, a summary diagram was developed to visually represent these risk scenarios and facilitate decision-making regarding its use (Figure 1).

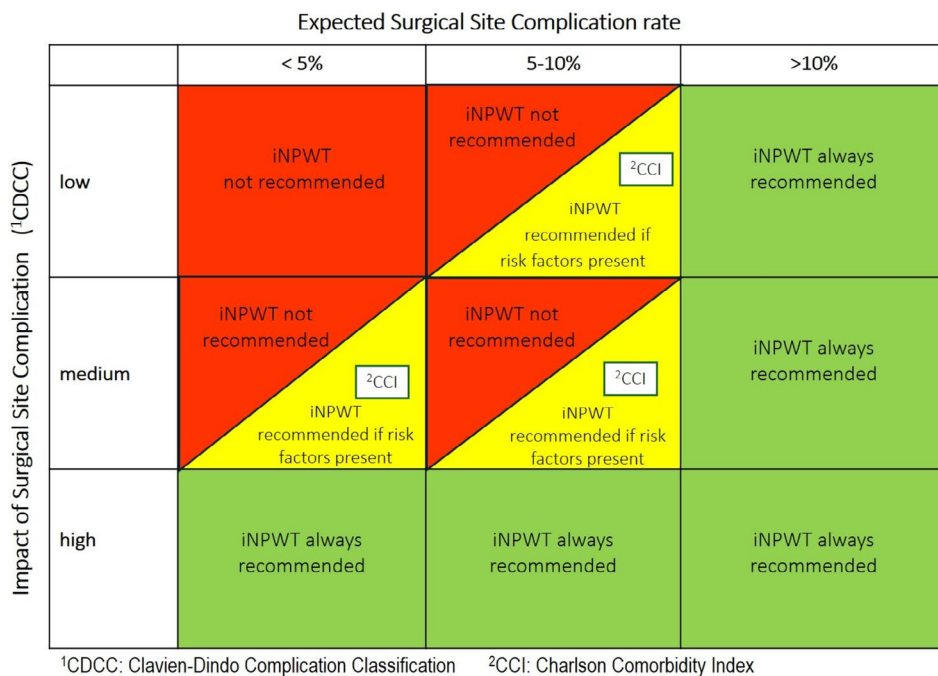
For this diagram, the authors classified interventions based on three expected levels of surgical site interventions and three levels of complication impact for cases where ciNPT may be applicable. The experts determined the ratio of complications using Medicare patient data [6] categorised by incidence rates (< 5%, 5%–10% and > 10%) and those of SSI reported by the CDC and the ECDC [109]. For complication impact, an adaptation of the Clavien–Dindo classification system [110] was used: low impact (Clavien 1), medium impact (Clavien 2) and high impact (Clavien ≥ 3). In this way, this classification was used to individually assess the clinical impact that an SSC would have in the various types of surgical procedures or incision-related situations within each surgical specialty (Table 4).

In the diagram, ciNPT is not recommended in low-risk (red zone) scenarios without identified risk factors (according to Tables 2 and 3); it is considered in intermediate-risk (yellow zone) settings when two or more risk factors are present (according to Bueno-Lledó et al. [111]), and it is strongly recommended in high-risk (green zone) cases, following specialty-specific criteria outlined in Table 4.

To more easily determine the presence of risk factors in patients, the expert group considered the CCI a good surrogate for patient risk factors and a simple tool for objective assessment of situations falling in the yellow area of the diagram in Figure 1. The CCI can, however, be combined with the factors specified in Tables 2 and 3. Based on the reviewed literature [6, 112], patients with a CCI score of 0–4 were categorised as low to moderate risk, while those with a CCI score greater than 5 were classified as high risk. Specific recommendations for the use of ciNPT tailored to each surgical specialty are provided in Table 4.

## 4 | Discussion

Numerous clinical studies and meta-analyses have demonstrated the efficacy of negative pressure therapy (NPWT) in promoting wound healing in open wounds of various aetiologies, including diabetic ulcers, pressure ulcers, open surgical wounds, and traumatic injuries [113–116]. These studies have consistently reported accelerated wound closure, reduced wound size, decreased bacterial burden, and enhanced granulation tissue formation with NPWT. The beneficial effects of NPWT on wound healing can be attributed to its multifaceted mechanisms of action: improvement of blood flow, reduction of



**FIGURE 1** | Decision-making algorithm for the use of ciNPT. The diagram illustrates risk-based recommendations for the use of ciNPT based on the expected surgical site complication rate (horizontal axis) and the clinical impact of such complications (vertical axis, based on the Clavien–Dindo Complication Classification). Red zones indicate scenarios where none of the risk factors listed in Tables 2 and 3 are present, and ciNPT is not recommended. Yellow zones represent intermediate-risk scenarios where ciNPT is recommended if two or more risk factors are present. Green zones correspond to high-risk situations in which ciNPT is always recommended, according to the specialty-specific indications detailed in Table 4.

oedema, stimulation of angiogenesis, management of exudate, promotion of granulation tissue formation, and modulation of the inflammatory response [117–119].

Surgeons have evolved the use of NPWT towards a prophylactic use on closed incisions, resulting in the concept of ciNPT. Since 2006, multiple randomised clinical studies and meta-analyses have been published in a variety of clinical settings. ciNPT is likely to protect the surgical incision by providing control of local factors such as decreasing oedema, controlling exudate, and reducing tension, and ensuring a tight seal [120].

Over the last decade, numerous meta-analyses have been published on the efficacy of ciNPT in influencing the frequency of SSIs and other local complications in surgical wounds. In addition, some consensus groups around the world have issued guidelines on this technology for specific surgical specialties or for all types of surgery [3, 12, 111, 121–124]. The present proposal compares well to and is aligned with these consensus documents. In general, the authors recommend the use of ciNPT selectively, in patients considered at “high risk” for adverse surgical wound events. However, in the authors’ opinion, the current guidelines do not sufficiently clarify a key element: the definition and stratification of risk factors that define the “high-risk” patient. Addressing this gap was the primary objective of the present consensus, aimed at, though not limited to, the surgical specialties represented in the Spanish OIC.

In this study, a considerable large number of meta-analyses have been detected. In this regard, it is interesting to note that prior to the 2016 World Health Organisation (WHO) meta-analysis, only three such reviews had been published. In contrast, 61

systematic reviews and meta-analyses have been published between 2020 and 2023. Some of these have been used for the development of clinical guidelines (WHO, National Institute for Health and Clinical Excellence, UK [NICE]) and some of the more recent ones used robust analysis techniques such as Cochrane methodology, GRADE qualification of evidence, and trial sequential analysis.

Of all the documents recovered, three deserve extensive comment. The 2022 update of the Cochrane review [9] concluded that wounds treated prophylactically with ciNPT probably have fewer SSIs (moderate-certainty evidence), but there is probably little or no difference in wound dehiscence (moderate-certainty evidence). They also found that people treated with ciNPT may experience more cases of skin blistering compared with those treated with standard dressings (low certainty evidence). There were no clear differences in other secondary outcomes where most of the evidence was of low or very low certainty. However, the review does not provide specific recommendations on when or in which clinical settings ciNPT should be used. On the other hand, the most recent meta-analysis, and probably the one with the most advanced methodology [13], employed a trial sequential analysis to assess the risk of random error. It concluded that the existing evidence is sufficient to affirm that the use of ciNPT is effective in reducing SSIs, and that future studies are very unlikely to influence the effect estimate for SSIs. Once again, the meta-analysis demonstrates the efficacy of ciNPT in high-risk patients, yet it fails to define who these patients are or which specific clinical situations should be considered high risk.

Finally, during the review phase of this manuscript, an additional international multidisciplinary consensus was published



[125]. Together with the results of our own consensus, its recommendations have contributed to the development of a mobile application (APP), *ciNPT Scorecard*, designed to support clinical decision-making regarding the use of ciNPT. The APP will be freely available in Spanish, Portuguese, and English, and is intended to assist healthcare professionals in the specialties represented in the consensus.

Each surgical specialty and each procedure has its own risk factors for SSCs. Also, patients' comorbidities, previous medications, and past medical history place them at different risk levels. In addition, the local characteristics of the surgical incision have to be taken into account when indicating whether or not to place a ciNPT device after wound closure. Most of the identified risk factors of SSIs were associated with patients' characteristics, highlighting male sex, age, high BMI, and diabetes as well as factors related to patients' lifestyle such as tobacco use. Obesity is associated with an altered immune response and skin tension [126], while diabetes contributes to angiogenesis dysregulation and affects the correct functioning of skin cells [127], resulting both in impaired wound healing. On the other hand, toxins present in cigarettes reduce skin cell migration, which affects the re-epithelialisation process and results in delayed wound healing and healing complications [128]. Overall, these factors should be taken into account prior to the surgical procedure.

Using the results of the review of meta-analyses and systematic reviews published in the literature and the experiences of the panel members, we sought to identify clinical scenarios in which the use of ciNPT may be beneficial in reducing surgical wound complications, including SSIs.

Treatment costs are an important part of healthcare and cannot be disregarded. Cost-effectiveness evaluations of ciNPT produced different results in different indications [9]. For example, previous publications have reported that the use of ciNPT in vascular patients resulted in a reduction of in-hospital complications, length of stay, and number of recurrent open wounds, resulting in reduced associated costs [129, 130]. In addition, another study assessing its use after closed surgical incisions showed an economic benefit compared with standard care, especially in patients with diabetes, BMI  $\geq 30$  kg/m<sup>2</sup> or ASA  $\geq 3$  [131]. In contrast, studies assessing the use of ciNPT after caesarean section in obese women could not conclude that this was a cost-effective approach [132, 133].

#### 4.1 | Limitations

This study has several limitations. As a consensus-based study, these ciNPT recommendations stem from the expertise of a panel of specialists selected for their experience in surgical infections and ciNPT research. While they provide clinical guidelines across surgical specialties, they remain subject to the panel's scope of knowledge, and surgical discretion should prevail in each case. Another potential limitation is the reliance on the Medicare database, a US registry that provides incidence rate data specific to its geographic population. The study's strengths include an extensive literature review and in-depth discussions conducted before establishing the recommendations.

Additionally, the panellists, representing nine different surgical specialties or subspecialties, provided broad regional representation across Spain.

In conclusion, the available literature enabled the panellists to identify risk factors related to the patient, wound, and surgical procedure. Combined with data on the incidence and impact of surgical complications, this evidence supports the development of recommendations for the use of ciNPT in clinical practise.

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#### Ethics Statement

The study is a consensus document among healthcare professionals. In accordance with the approved study protocol, participants were considered to have implicitly given informed consent by participating in the process. As the data used in the review are publicly available, and no patients participated in the study, patient consent was not required for publication.

#### Conflicts of Interest

All authors received an honorarium for attending the expert panel meeting. J.M.B. has received honorarium for educational activities and lectures from: BD, Smith+Nephew, Hartmann. I.R.P. has received honorarium for educational activities, lectures and as advisor from: BD, Medtronic, J&J, Smith+Nephew, Thermofisher.

#### Data Availability Statement

Data are from literature reviews and were generated by the authors.

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### Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Table S1:** Definitions of surgical site complications used in the study.