December 14, 2021

Smith and Nephew Medical Limited
Steeve Lamvohee
Director, Regulatory Affairs, Advanced Wound Management
101 Hessle Road
Hull, Yorkshire HU3 2BN
United Kingdom

Re: K203716
Trade/Device Name: PICO Single Use Negative Pressure Wound Therapy System, PICO 7 Single Use Negative Pressure Wound Therapy System, PICO 7Y Single Use Negative Pressure Wound Therapy System, PICO 14 Single Use Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4783
Regulation Name: Negative Pressure Wound Therapy Device For Reduction Of Wound Complications
Regulatory Class: Class II
Product Code: QFC
Dated: June 1, 2021
Received: June 14, 2021

Dear Steeve Lamvohee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203716

Device Name
PICO Single Use Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
PICO Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO Single Use Negative Pressure Wound Therapy Systems are suitable for use both in a hospital and homecare setting. Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

When used on closed surgical incisions, PICO Single Use Negative Pressure Wound Therapy System is intended to aid in reducing the incidence of:

- Superficial and deep incisional surgical site infections for high risk patients in Class I and Class II wounds
- Post-operative seroma
- Dehiscence

Note: When used on closed incisions for the reduction of SSI, the safety and effectiveness for Class III (contaminated) and Class IV (Dirty/Infected) wounds have not been demonstrated. Furthermore, Class IV surgical wounds are not expected to be closed primarily. The device has not been demonstrated to reduce organ space surgical site infections. The device is intended to aid in reducing the incidence of, but not treat, seroma, dehiscence, or infected wounds - the use of PICO does not preclude the need to develop and follow a comprehensive infection management protocol.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203716

Device Name
PICO 7 Single Use Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
PICO 7 Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO 7 Single Use Negative Pressure Wound Therapy Systems are suitable for use both in a hospital and homecare setting. Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

When used on closed surgical incisions, PICO 7 Single Use Negative Pressure Wound Therapy System is intended to aid in reducing the incidence of:

- Superficial and deep incisional surgical site infections for high risk patients in Class I and Class II wounds
- Post-operative seroma
- Dehiscence

Note: When used on closed incisions for the reduction of SSI, the safety and effectiveness for Class III (contaminated) and Class IV (Dirty/Infected) wounds have not been demonstrated. Furthermore, Class IV surgical wounds are not expected to be closed primarily. The device has not been demonstrated to reduce organ space surgical site infections.The device is intended to aid in reducing the incidence of, but not treat, seroma, dehiscence, or infected wounds - the use of PICO does not preclude the need to develop and follow a comprehensive infection management protocol.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203716

Device Name
PICO 7Y Single Use Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
PICO 7Y Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO 7Y Single Use Negative Pressure Wound Therapy Systems are suitable for use both in a hospital and homecare setting. Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

When used on closed surgical incisions, PICO 7Y Single Use Negative Pressure Wound Therapy System is intended to aid in reducing the incidence of:

- Superficial incisional surgical site infections for high risk patients in Class I wounds
- Post-operative seroma
- Dehiscence

Note: When used on closed incisions for the reduction of SSI, the safety and effectiveness for Class II (Clean/ Contaminated), Class III (contaminated) and Class IV (Dirty/Infected) wounds have not been demonstrated. Furthermore, Class IV surgical wounds are not expected to be closed primarily. The device has not been demonstrated to reduce organ space surgical site infections. The device is intended to aid in reducing the incidence of, but not treat, seroma, dehiscence, or infected wounds - the use of PICO does not preclude the need to develop and follow a comprehensive infection management protocol.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203716

Device Name
PICO 14 Single Use Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
PICO 14 Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO 14 Single Use Negative Pressure Wound Therapy Systems are suitable for use both in a hospital and homecare setting. Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

When used on closed surgical incisions for up to 7 days, PICO 14 Single Use Negative Pressure Wound Therapy is intended to aid in reducing the incidence of:

- Superficial and deep incisional surgical site infections for high risk patients in Class I and Class II wounds
- Post-operative seroma
- Dehiscence

Note: When used on closed incisions for the reduction of SSI, the safety and effectiveness for Class III (contaminated) and Class IV (Dirty/Infected) wounds have not been demonstrated. Furthermore, Class IV surgical wounds are not expected to be closed primarily. The device has not been demonstrated to reduce organ space surgical site infections. The device is intended to aid in reducing the incidence of, but not treat, seroma, dehiscence, or infected wounds - the use of PICO does not preclude the need to develop and follow a comprehensive infection management protocol.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

21 CFR 807.92 (a)(1): Submitter's Information	
510(k) Owner Name	Smith & Nephew Medical Ltd
Address	101 Hessle Road, Hull, HU3 2BN, United Kingdom
Establishment Registration Number	8043484
Contact Name	Dr Steeve Lamvohee, Regulatory Affairs Director
Date Prepared	23 Sept 2021
21 CFR 807.92 (a)(2): Device Information	
Device Name (Trade/Proprietary Name)	PICO Single Use Negative Pressure Wound Therapy System PICO 7 Single Use Negative Pressure Wound Therapy System PICO 7Y Single Use Negative Pressure Wound Therapy System PICO 14 Single Use Negative Pressure Wound Therapy System
Common Name	Negative pressure wound therapy device for reduction of wound complications
Review Panel	General and Plastic Surgery
Regulation Number	21 CFR 878.4783
Regulatory Class	Class II
Product Code	QFC
21 CFR 807.92 (a)(3): Legally marketed device to which equivalence is claimed	**DeNovo Number:** DEN180013 **Device Name:** PREVENA^{TM} 125 and PREVENA PLUS^{TM} 125 (PREVENA)

21 CFR 807.92 (a)(4): Device Description

The PICO Family of devices, PICO (cleared under K163387), PICO 7 (cleared under K180698), PICO 7Y (cleared under K182323), PICO 14 (cleared under K191760) all have the same main function of management of fluid through dressing absorbency and evaporation with added benefit of negative pressure. The pump provides a -80mmHg nominal pressure under the dressing, applying Negative Pressure Wound Therapy (NPWT) to the wound. The PICO Single Use Negative Therapy Systems consist of:

- PICO Pump
- Dressing (s)
- Fixation strips
- Batteries
- Connection tubing
- Instructions for Use

The system is a canister-less system - fluid is managed by the dressing. The pump that delivers the NPWT is a portable, battery-powered, software-controlled system that can provide continuous application of negative pressure to the wound as a delivery pressure at a nominal value of -80mmHg. The PICO Systems are designed to be used at home or within a healthcare setting by an appropriate healthcare professional.

The dressing and amount of negative pressure delivered across all systems remain the same. **Table 1** provides details of products within the PICO Family.

In the context of the proposed Indications for Use, see the definitions provided:

According to the latest recommendations (CDC 2020), superficial and deep incisional SSIs are defined as follows:

- A superficial incisional SSI involves only skin and subcutaneous tissue of the incision and occurs within 30 days after any National Healthcare Safety Network (NHSN) operative procedure.
- A deep incisional SSI involves deep soft tissues of the incision (for example, fascial and muscle layers) and occurs within 30 or 90 days after the NHSN operative procedure.

Reference:
CDC 2020. SSI – Procedure-associated Module 2020. Available from: https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf. [Accessed 04/11/2020].

TABLE 1: Comparison of PICO Family

	PICO (PICO 1.6)	PICO 7	PICO 7Y	PICO 14
Indications for Use	PICO Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO Single Use Negative Pressure Wound Therapy Systems are suitable for use both in a hospital and homecare setting. Appropriate wound types include: • Chronic • Acute • Traumatic • Subacute and dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic or pressure) • Flaps and grafts • Closed surgical incisions When used on closed surgical incisions, PICO Single Use Negative Pressure Wound Therapy System is intended to aid in reducing the incidence of: • Superficial and deep incisional surgical site	Same as PICO (PICO 1.6)	PICO 7Y Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO 7Y Single Use Negative Pressure Wound Therapy Systems are suitable for use both in a hospital and homecare setting. Appropriate wound types include: • Chronic • Acute • Traumatic • Subacute and dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic or pressure) • Flaps and grafts • Closed surgical incisions When used on closed surgical incisions, PICO 7Y Single Use Negative Pressure Wound Therapy System is intended to aid in reducing the incidence of: • Superficial incisional surgical site	PICO 14 Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO 14 Single Use Negative Pressure Wound Therapy Systems are suitable for use both in a hospital and homecare setting. Appropriate wound types include: • Chronic • Acute • Traumatic • Subacute and dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic or pressure) • Flaps and grafts • Closed surgical incisions When used on closed surgical incisions for up to 7 days, PICO 14 Single Use Negative Pressure Wound Therapy is intended to aid in reducing the incidence of: • Superficial and deep incisional

	PICO (PICO 1.6)	PICO 7	PICO 7Y	PICO 14
	infections for high risk patients in Class I and Class II wounds • Post-operative seroma • Dehiscence Note: When used on closed incisions for the reduction of SSI, the safety and effectiveness for Class III (contaminated) and Class IV (Dirty/Infected) wounds have not been demonstrated. Furthermore, Class IV surgical wounds are not expected to be closed primarily. The device has not been demonstrated to reduce organ space surgical site infections. The device is intended to aid in reducing the incidence of, but not treat, seroma, dehiscence, or infected wounds - the use of PICO does not preclude the need to develop and follow a comprehensive infection management protocol.		infections for high risk patients in Class I wounds • Post-operative seroma • Dehiscence Note: When used on closed incisions for the reduction of SSI, the safety and effectiveness for Class II (Clean/Contaminated), Class III (contaminated) and Class IV (Dirty/Infected) wounds have not been demonstrated. Furthermore, Class IV surgical wounds are not expected to be closed primarily. The device has not been demonstrated to reduce organ space surgical site infections. The device is intended to aid in reducing the incidence of, but not treat, seroma, dehiscence, or infected wounds - the use of PICO does not preclude the need to develop and follow a comprehensive infection management protocol.	surgical site infections for high risk patients in Class I and Class II wounds • Post-operative seroma • Dehiscence Note: When used on closed incisions for the reduction of SSI, the safety and effectiveness for Class III (contaminated) and Class IV (Dirty/Infected) wounds have not been demonstrated. Furthermore, Class IV surgical wounds are not expected to be closed primarily. The device has not been demonstrated to reduce organ space surgical site infections. The device is intended to aid in reducing the incidence of, but not treat, seroma, dehiscence, or infected wounds - the use of PICO does not preclude the need to develop and follow a comprehensive infection management protocol.
Technological principal for delivering the negative pressure wound therapy	Removal of air from dressing and wound creating NPWT effect. Dressing absorbs exudate from wound which then evaporates	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)

	PICO (PICO 1.6)	PICO 7	PICO 7Y	PICO 14
Physical components of the pumps	Electric motor driven twin-diaphragm vacuum pump controlled by Microprocessor	Custom designed "voice-coil" Pump containing a magnet controlled by Microprocessor	Same as PICO 7	Same as PICO 7
Physical components of Dressing	Dressing: High Moisture Vapor Permeability polyurethane (MVP PU) top film, polyester spacer layer, air laid super absorbent, silicone wound contact layer, Soft Port tube Secondary fixation strips: High MVP film with acrylic adhesive	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)
Tubing/Dressing connector	Single – used to connect a single dressing to the device using PVC tubing	Same as PICO (PICO 1.6)	Y shaped – used to connect two dressings to the device using two sets of PVC tubing; same amount of negative pressure delivered to each wound as PICO (PICO 1.6), PICO 7, and PICO 14	Same as PICO (PICO 1.6)
Batteries	AA Lithium (2)	AA Alkaline (2)	Same as PICO (PICO 1.6)	AA Alkaline (2) + 2 spares provided
Software Controlled	Yes	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)
Dressing Wear Time	Up to 7 Days	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)
Pump Lifetime	7 Days	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)	14 Days
User Interface	After dressing application, the user would interact with the pump device that is attached to the dressing via a soft-port. The pump	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)

	PICO (PICO 1.6)	PICO 7	PICO 7Y	PICO 14
	device has a start/stop therapy button and indicators.			
Electrical Safety and Electro-magnetic Compatibility (EMC)	Complies with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-1-6, IEC 62366	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)
Dimensions	63mm x 70mm x 18mm	2.6 x 3.2 x 0.9”	Same as PICO 7	Same as PICO 7
Operating Pressure at Wound Treatment Location	Nominal -80mmHg	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)	Same as PICO (PICO 1.6)

21 CFR 807.92 (a)(5): Intended Use / Indications for Use

PICO and PICO 7

PICO/PICO 7 Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO / PICO 7 Single Use Negative Pressure Wound Therapy Systems are suitable for use both in a hospital and homecare setting. Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

When used on closed surgical incisions, PICO/ PICO 7 Single Use Negative Pressure Wound Therapy System is intended to aid in reducing the incidence of:

- Superficial and deep incisional surgical site infections for high risk patients in Class I and Class II wounds
- Post-operative seroma
- Dehiscence

PICO 7Y

PICO 7Y Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO 7Y Single Use Negative Pressure Wound Therapy Systems are suitable for use both in a hospital and homecare setting. Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

When used on closed surgical incisions, PICO 7Y Single Use Negative Pressure Wound Therapy System is intended to aid in reducing the incidence of:

- Superficial incisional surgical site infections for high risk patients in Class I wounds
- Post-operative seroma
- Dehiscence

PICO 14

PICO 14 Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO 14 Single Use Negative Pressure Wound Therapy Systems are suitable for use
both in a hospital and homecare setting. Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

When used on closed surgical incisions for up to 7 days, PICO 14 Single Use Negative Pressure Wound Therapy is intended to aid in reducing the incidence of:

- Superficial and deep incisional surgical site infections for high risk patients in Class I and Class II wounds
- Post-operative seroma
- Dehiscence

21 CFR 807.92 (a)(6): Comparison of Technological Characteristics between the Subject and Predicate Devices

The PICO Family and the cleared PREVENA device have very similar indications for use, similar technological characteristics and the same principles of operation. While there are minor technological differences between the PICO Family and PREVENA with respect to exudate management, therapeutic pressure setting, device sterility status and dimensions, these differences do not raise any new or different questions of safety and effectiveness compared to the predicate device, see **Table 2** below.

Table 2: Comparison of PICO Family against PREVENA

	PREVENA (Predicate Device)	**PICO Family (Subject Device)**
Product Type	Single patient / Disposable	Single patient / Disposable
Product Code	QFC (21 C.F.R. § 878.4783)	QFC (21 C.F.R. § 878.4783)
Product Classification	Reclassified as Class II	Class II
Exudate management system	Canister	Absorbent dressing
Therapeutic pressure	-125mmHg	-80mmHg
Dressing Wear Time	7 days	Up to 7 days
Intended Use	Indicated for patients who would benefit from a suction device (NPWT) to promote wound healing via removal of low to moderate levels of exudate and infectious materials.	Indicated for patients who would benefit from a suction device (NPWT) to promote wound healing via removal of low to moderate levels of exudate and infectious materials.
Indications for use	PREVENA 125 and PREVENA PLUS 125 Therapy Units manage the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of -125mmHg continuous negative pressure. When used with legally marketed compatible dressings, PREVENA 125 and PREVENA PLUS 125 Therapy Units are intended to aid in reducing the incidence of seroma and, in patients at high risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds	PICO Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO Single Use Negative Pressure Wound Therapy Systems are suitable for use both in a hospital and homecare setting. Appropriate wound types include: • Chronic • Acute • Traumatic • Subacute and dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic or pressure) • Flaps and grafts • Closed surgical incisions

		When used on closed surgical incisions, PICO Single Use Negative Pressure Wound Therapy System is intended to aid in reducing the incidence of: • Superficial and deep incisional surgical site infections for high risk patients in Class I and Class II wounds • Post-operative seroma • Dehiscence
		PICO 7 Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO 7 Single Use Negative Pressure Wound Therapy Systems are suitable for use both in a hospital and homecare setting. Appropriate wound types include: • Chronic • Acute • Traumatic • Subacute and dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic or pressure) • Flaps and grafts • Closed surgical incisions When used on closed surgical incisions, PICO 7 Single Use Negative Pressure Wound Therapy System is intended to aid in reducing the incidence of: • Superficial and deep incisional surgical site infections for high risk patients in Class I and Class II wounds • Post-operative seroma • Dehiscence
		PICO 7Y Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious

		materials. PICO 7Y Single Use Negative Pressure Wound Therapy Systems are suitable for use both in a hospital and homecare setting. Appropriate wound types include: • Chronic • Acute • Traumatic • Subacute and dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic or pressure) • Flaps and grafts • Closed surgical incisions When used on closed surgical incisions, PICO 7Y Single Use Negative Pressure Wound Therapy System is intended to aid in reducing the incidence of: • Superficial incisional surgical site infections for high risk patients in Class I wounds • Post-operative seroma • Dehiscence
		PICO 14 Single Use Negative Pressure Wound Therapy System is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO 14 Single Use Negative Pressure Wound Therapy Systems are suitable for use both in a hospital and homecare setting. Appropriate wound types include: • Chronic • Acute • Traumatic • Subacute and dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic or pressure) • Flaps and grafts • Closed surgical incisions

		When used on closed surgical incisions for up to 7 days, PICO 14 Single Use Negative Pressure Wound Therapy is intended to aid in reducing the incidence of: • Superficial and deep incisional surgical site infections for high risk patients in Class I and Class II wounds • Post-operative seroma • Dehiscence
Limitations	• The device is not intended to treat surgical site infection or seroma. • Safety and effectiveness in pediatric population (<22 years old) have not been evaluated. • Safety and effectiveness in Class III (Contaminated) and Class IV (Dirty/Infected) wounds have not been demonstrated. Furthermore, Class IV surgical wounds are not expected to be closed primarily, and the subject device should only be used on closed surgical incisions. • The device has not been demonstrated to reduce deep incisional and organ space surgical site infections. • The device has not been demonstrated to be effective in reducing the incidence of surgical site infection and seroma in all surgical procedures and patient populations; therefore, the device may not be recommended for routine use to reduce the incidence of surgical site infection and seroma.	<u>PICO, PICO 7, PICO 14</u> Note: When used on closed incisions for the reduction of SSI, the safety and effectiveness for Class III (contaminated) and Class IV (Dirty/Infected) wounds have not been demonstrated. Furthermore, Class IV surgical wounds are not expected to be closed primarily. The device has not been demonstrated to reduce organ space surgical site infections. The device is intended to aid in reducing the incidence of, but not treat, seroma, dehiscence, or infected wounds - the use of PICO does not preclude the need to develop and follow a comprehensive infection management protocol. <u>PICO 7Y</u> Note: When used on closed incisions for the reduction of SSI, the safety and effectiveness for Class II (Clean/Contaminated), Class III (contaminated) and Class IV (Dirty/Infected) wounds have not been demonstrated. Furthermore, Class IV surgical wounds are not expected to be closed primarily. The device has not been demonstrated to reduce organ space surgical site infections. The device is intended to aid in reducing the incidence of, but not treat, seroma, dehiscence, or infected wounds - the use of PICO does not preclude the need to develop and follow a comprehensive infection management protocol

21 CFR 807.92 (b)(1): Brief discussion of nonclinical tests submitted/referenced/ relied on in this submission to determine substantial equivalence

Non-clinical/bench test data (including biocompatibility, shelf life/stability, electrical safety and electromagnetic compatibility (EMC), software, performance testing, and human factors/usability testing) were referenced from the following previously-cleared 510(k) submissions of the PICO device: K163387, K180698, K182323, K191760.

Additional EMC testing on PICO 7 was conducted in accordance with IEC 60601-1-2:2014 to demonstrate that alternative suppliers of electrical components did not negatively impact EMC.

21 CFR 807.92 (b)(2): Brief discussion of clinical tests submitted/referenced/ relied on in this submission to determine substantial equivalence

1. CLINICAL DATA

A systematic literature review and associated meta-analyses were used to support the safety and effectiveness of the PICO Family over closed incisions in reducing the incidence of surgical site infections (SSIs), seromas and dehiscence versus conventional wound dressings.

Database search and study selection:

A comprehensive review of published PICO Family literature identified relevant articles to support a reduction in SSI, seroma, and dehiscence. Three databases (PubMed, EMBASE and the Cochrane Library) were used to identify published clinical studies. The exact search terms used for each of the three databases are detailed in **Table 1**. Registered studies at ClinicalTrials.gov were also reviewed using the same search terms for completed and terminated studies with results available (**Table 1**).

Table 1. Search strings and filters used for each of the database searches.

Database	Search query	Filters / Limits	Search hits
PubMed	("Negative Pressure Wound Therapy"[All Fields] OR "NPWT"[All Fields] OR "PICO"[All Fields] OR "Topical Negative Pressure"[All Fields]) AND (2011/1/1:2021/4/19[pdat])	Date: 01/01/2011 to 19/04/2021 Searched: All Fields	6581
EMBASE	('negative pressure wound therapy' OR 'npwt' OR 'pico' OR 'topical negative pressure') AND [1-1-2011]/sd NOT [20-4-2021]/sd	Date: 01/01/2011 to 19/04/2021 (Date added to EMBASE) Searched: All Fields	7711

Cochrane Library	("Negative Pressure Wound Therapy" OR "NPWT" OR "PICO" OR "Topical Negative Pressure") (Word variations have been searched)	Date: Jan 2011 to Apr 2021 Searched: All Text	852
ClinicalTrials.gov	"Negative Pressure Wound Therapy" OR "NPWT" OR "PICO" OR "Topical Negative Pressure"	Date: 01/01/2011 to 19/04/2021 'Results available'	139

Two (2) independent reviewers performed the study selection. Abstracts that met the search criteria were screened and assessed against inclusion and exclusion criteria provided in **Table 2**. If either reviewer deemed an article as potentially relevant, then the article progressed to full text screening. In case of disagreement a third reviewer made the final decision after reading the full text paper or conference abstract. Included studies detailed outcomes following the use of PICO compared to standard care for closed surgical incisions. The standard of care was defined as the use of standard non-NPWT dressings.

Table 2. Inclusion and Exclusion Criteria.

Inclusion Criteria		**Exclusion Criteria**
Population	Patients of any age with closed surgical incisions. Patients with any risk factors for complications were also included.	Patients with open surgical incisions or any non-surgical wound
Intervention	PICO (single-use NPWT) applied post-operatively on a closed surgical incision. Participants undergoing any type of operation were eligible.	Other forms of NPWT (i.e. not PICO) were excluded.
Comparator	Standard care (any non-NPWT dressing)	Non-standard care
Outcome	Surgical site infections or seroma or dehiscence	N/A
Study design	Randomised controlled trials or prospective observational studies with at least 10 patients in each treatment arm	Retrospective observational studies, case reports, case-series, studies with less than 10 patients in each treatment arm, letters, commentaries, notes, reviews and editorials
Language restrictions	English	Not in English

Search dates	Studies published from 01 Jan 2011 to 19 Apr 2021	Studies published before 2011

Data extraction and quality assessment:
Data was extracted from included studies by one reviewer using a predefined and standardized data extraction form and checked by a second reviewer for accuracy. Extracted data included descriptions of study design, location of study, the number of patients, patient demographic data, and the type of surgery. Outcomes pertaining to SSI, seroma and dehiscence in closed surgical incisions were also extracted and evaluated. Quality assessment of studies was made according to two well-established guidelines. Randomized controlled trials were assessed according to the quality criteria from the Centre for Reviews and Dissemination (CRD) guidelines[1]. Prospective observational studies were assessed according to adapted criteria from the Critical Appraisal Skills Programme (CASP)[2].

Summary of the clinical data identified:
Ultimately, twenty-five (25)[3-23,27-30] articles were deemed to be relevant to the systematic literature review and used for the meta-analysis for SSI, seroma and dehiscence characterization (SSC). This consisted of seventeen (17) randomized controlled trials and eight (8) prospective observational studies. A total of up to 5,673 evaluable patients were included in these meta-analyses with 2,737 in the PICO Family therapy (treatment) group and 2,936 in the SOC (control) group. A summary of the articles identified in the review and those eligible for meta-analysis is provided in **Figure 1** and **Figure 2**.

Figure 1: Study Selection for the Meta-Analysis of Reduction of Wound Complications: Infection, Seroma and Dehiscence

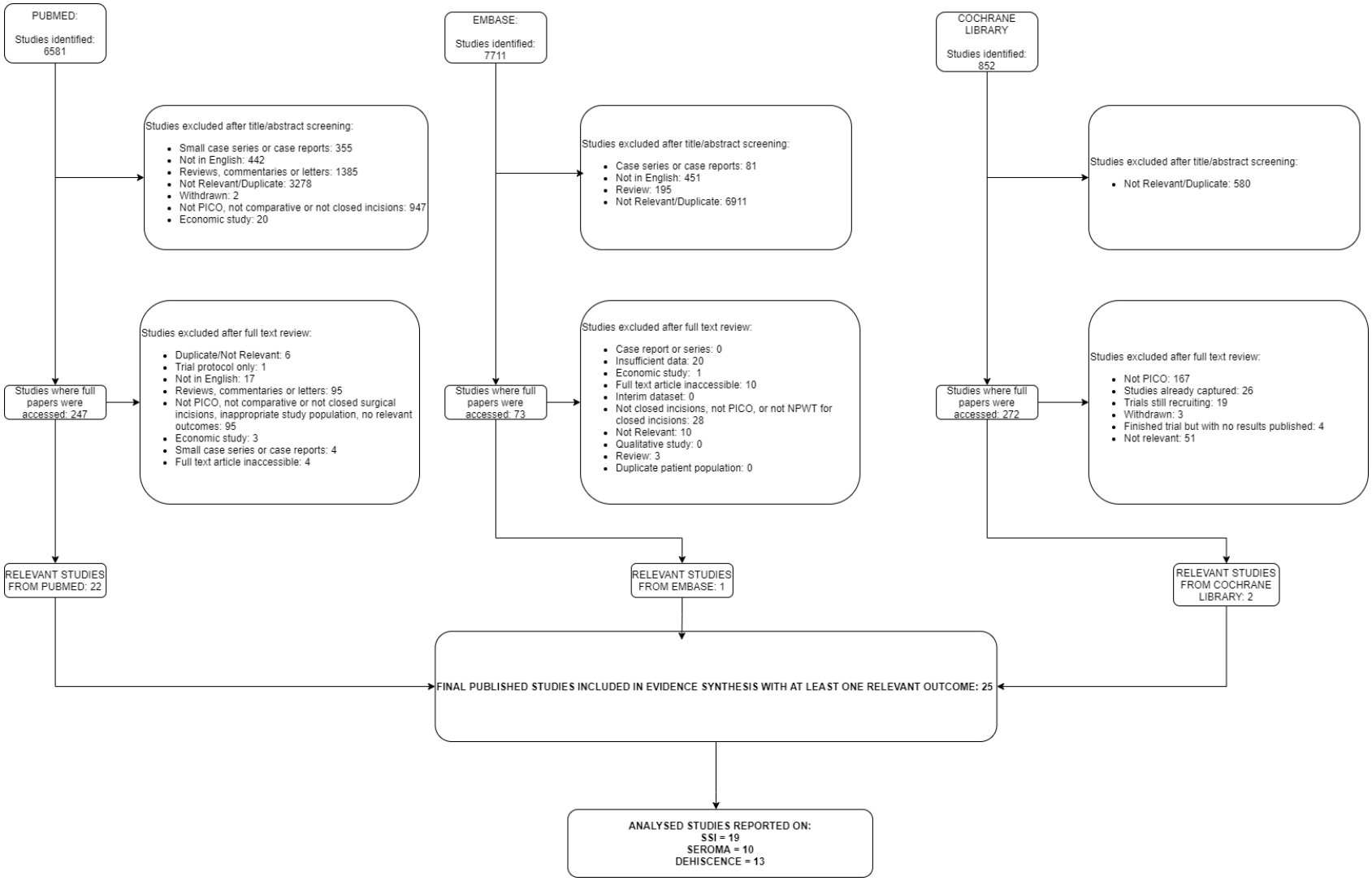
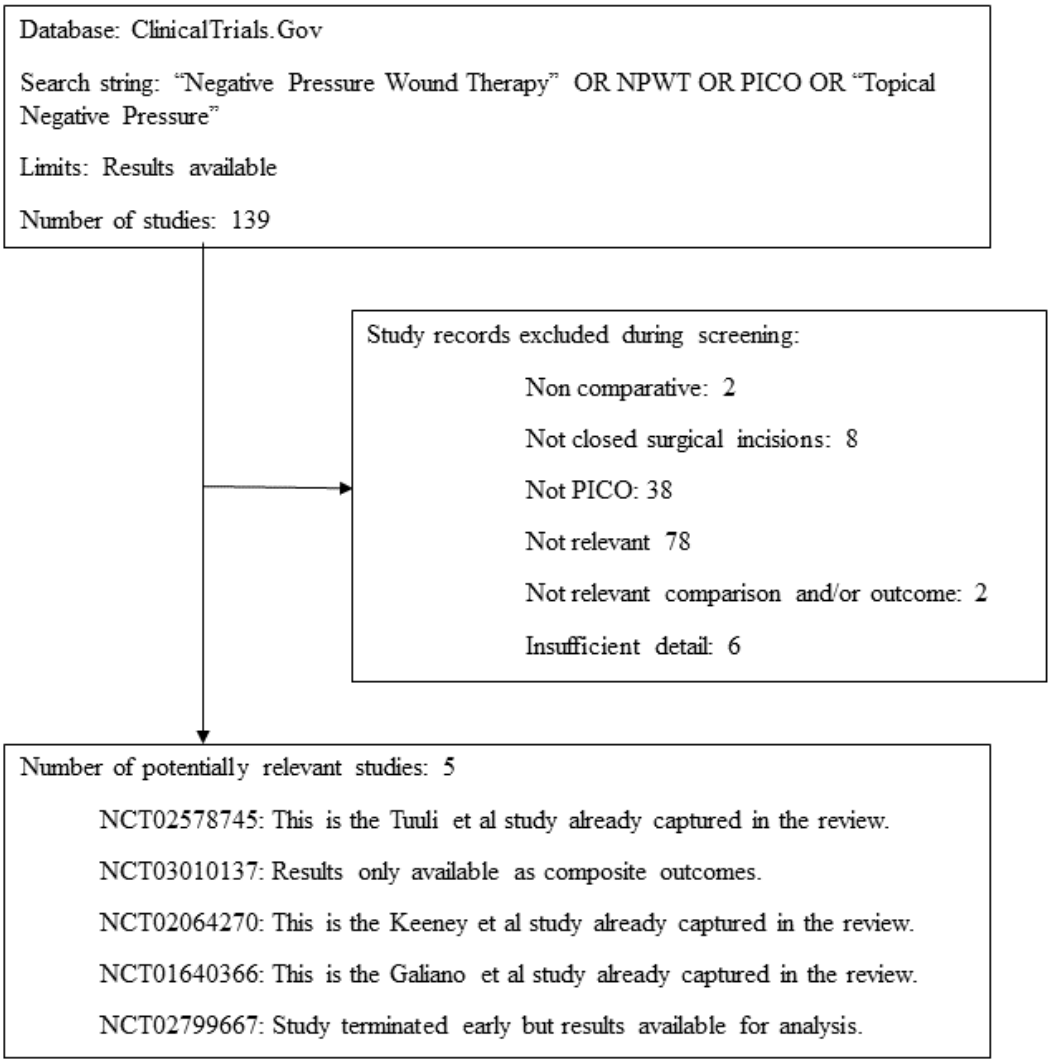


Figure 2: Study Selection from the ClinicalTrials.gov database



2. SURGICAL SITE INFECTION (SSI)

A systematic literature review is included to demonstrate that the PICO Family can reduce the incidence of surgical site infections in closed surgical incisions in high risk patients in Class I and Class II wounds. Clinical studies which followed-up patients for at least 30 days (as defined by CDC guidelines[24]) were included in the analysis. A study was considered to contain 'high risk' patients if the majority (> 50%) of patients treated with PICO in that study presented with at least one 'intrinsic' or 'extrinsic' risk factor, as defined by the American College of Surgeons (ACS) and Surgical Infection Society's Surgical Site Infection Guidelines[25].

Literature Support (Reduction in SSI for High Risk Patients)

Meta-analysis of the seventeen (17) studies relevant to SSI demonstrates a statistically significant reduction in the odds of developing an infection when using PICO Family therapy in comparison to standard surgical dressing (SOC). Of the seventeen (17) prospective studies included in the meta-analysis for infection:

- Twelve (12) studies were randomized controlled trials and considered Level I evidence
- Five (5) studies were considered Level II evidence, which are non-randomized prospective observational studies

See **Table 3** below for a complete description of these studies.

Table 3. Published Studies Evaluating Reduction in Infection for High Risk Patients

Study	Study design	Surgical Procedure	Identified potential risk factors for surgical site infections	Study duration	Incisional dressings used	No. of Subjects	Treatment duration
Gillespie *et al* 2015	RCT	Elective primary hip arthroplasty patients	The majority of patients had a ASA score of ≥2	6 weeks	PICO dressing	35	5 days
					Comfeel dressing reinforced with 2 absorbent dressings, and then with a self-adhesive, non-woven tape	35	Left intact and patients were discharged with their original dressing
Hyldig *et al* 2018	RCT	Elective and emergency caesarean section patients	Inclusion criterion of BMI ≥30kg/m^2	30 days	PICO dressing	432	5 days
					Standard postoperative dressing	444	The dressing was left *in situ* for at least 24 hours
Karlakki *et al* 2016	RCT	Patients undergoing elective hip and knee arthroplasty	The majority of patients had a raised BMI and ASA score. The mean age of participants was >65 years old	6 weeks	PICO dressing	102	4 days or longer
					Comfeel dressing	107	Dressing was left on for 4 days, or longer if drainage continued, unless soiled or dislodged.

Study	Study design	Surgical Procedure	Identified potential risk factors for surgical site infections	Study duration	Incisional dressings used	No. of Subjects	Treatment duration
O'Leary *et al* 2017	RCT	Laparotomy patients who received open abdominal surgery	The majority of patients had a raised BMI and ASA score Type of surgery	30 days	PICO dressing	24	4 days
					Transparent waterproof dressing (Smith & Nephew)	25	4 days
Uchino *et al* 2016	RCT	Patients with ulcerative colitis undergoing elective ileostomy closure	All patients had a raised ASA score; inclusion criterion of patients with ulcerative colitis	Patients visited the clinic 4 weeks after the discharge, and every 4 weeks thereafter if they presented with complications	PICO dressing	28	Continued for 2 weeks, with exchange every 3–4 days
					Simple adhesive plaster	31	Not Reported
Witt-Majchrzak *et al* 2015	RCT	Patients undergoing coronary artery bypass grafting surgery	The majority of patients had a raised BMI and co-morbidities; Prolonged	6 weeks	PICO dressing	40	Applied for up to 6 days. Dressing changed on day 2 or 3 and removed on day 5 or 6 after surgery

Study	Study design	Surgical Procedure	Identified potential risk factors for surgical site infections	Study duration	Incisional dressings used	No. of Subjects	Treatment duration
			duration of surgery		Conventional dressing	40	Dressings changed daily
					Conventional dressing	92	Dressings remained *in situ* for seven days, or until the day of discharge if they went home earlier, unless there was suspicion of infection or the dressing was soaked or leaking.
Hasselmann *et al* 2019	RCT	Patients undergoing elective open vascular surgery with inguinal incisions	The majority of patients had pre-existing co-morbidities	90 days	PICO dressing	78	The PICO device and dressing was left in place for seven days post-operatively, after which patients were instructed to remove it
					Vitri Pad; ViTri Medical,	80	Unless an unplanned change

Study	Study design	Surgical Procedure	Identified potential risk factors for surgical site infections	Study duration	Incisional dressings used	No. of Subjects	Treatment duration
					Saltsjo¨-Boo, Sweden or OPSITE Post-Op Visible; Smith and Nephew, London, UK		had to be conducted, the standard dressing was left in place for at least 48 hours, although changes due to moisture build-up was an issue on the standard dressing side and dressing changes did sometimes happen prior to 48 hours post-operatively
Keeney *et al* 2019	RCT	Patients undergoing primary or revision lower extremity TJA	43.0% of hip patients and 55.5% of knee patients had a BMI > 35 kg/m^2	35 days	PICO dressing	185	Initial period of 7 days
					Non-adherent incisional cover (Adaptic or Xeroform gauze)	213	Dressings were changed on postoperative day 2 with subsequent dressing changes performed at 3- to

Study	Study design	Surgical Procedure	Identified potential risk factors for surgical site infections	Study duration	Incisional dressings used	No. of Subjects	Treatment duration
							5-day intervals until the incision was dry
Dingemans *et al* 2018	Prospective and historical controlled	Patients with foot or ankle fractures	Type of surgery	30 days	PICO dressing	47	7 days
					Conventional surgical dressings	47	For the control arm of the study, patients received a pressure bandage with gauze placed underneath, usually for three days duration.
Pellino *et al* 2014a	Prospective observational study	Patients (50 undergoing breast surgery, 50 colorectal surgery)	Type of surgery Prolonged duration of surgery	3 months	PICO dressing	50	7 days
					Basic wound contact absorbent dressings	50	Sterile removal for control after 48 h. On post-operative day 3, gauzes were removed sterilely and wounds left

Study	Study design	Surgical Procedure	Identified potential risk factors for surgical site infections	Study duration	Incisional dressings used	No. of Subjects	Treatment duration
							exposed if no complications occurred.
Pellino *et al* 2014b	Prospective observational	Crohn's disease patients undergoing small bowel resection	Type of surgery The majority of patients had co-morbidities and raised ASA score	3 months	PICO dressing	13	7 days
					Basic wound contact absorbent dressings	17	Sterile removal for control after 48 h. On postoperative day 3, gauzes were removed sterilely and wounds left exposed if no complications occurred
Selvaggi *et al* 2014	Prospective observational study	Crohn's disease patients undergoing abdominal surgery	Type of surgery The majority of patients had co-morbidities	3 months	PICO dressing	25	7 days
					Basic wound contact absorbent dressings	25	Sterile removal for control after 48 h. On postoperative day 3, gauzes were removed sterilely and wounds left.

Study	Study design	Surgical Procedure	Identified potential risk factors for surgical site infections	Study duration	Incisional dressings used	No. of Subjects	Treatment duration
Tuuli *et al* 2017	RCT / Conference Abstract	Caesarean section patients	Inclusion criterion of a BMI ≥30kg/m^2	30 days	PICO dressing	60	Removed at discharge (usually on day 4)
					Standard wound dressing	60	The dressing was removed after hours
Martin and O'Neil 2020	RCT / Conference Abstract	Patients undergoing hepatectomy and pancreatectomy.	The average age among all participants was 60.82 years and BMI was 31.7.	1 year	PICO dressing	20	For the PICO arm of the study, the PICO device was left in place for a total of 7 days.
					Sterile island dressing	20	For the control arm of the study, the length of time the dressing was left in place for was a median on 5 days (range 2-5 days).
Helito *et al* 2020	Prospective and historical controlled	Patients undergoing total knee arthroplasty	The majority of patients (51.7%) had at least one risk factor for	12 months	PICO dressing	97	Applied with an intentional duration of 7 days.

Study	Study design	Surgical Procedure	Identified potential risk factors for surgical site infections	Study duration	Incisional dressings used	No. of Subjects	Treatment duration
			surgical wound complications		Conventional surgical dressings	199	Applied with an intentional duration of 7 days.
Costa *et al* 2020	RCT	Patients undergoing surgery for lower limb fractures associated with major trauma	Type of surgery	6 months	PICO dressing	770	Applied according to surgeon's normal practice and the manufacturer's instructions (up to 7 days of treatment).
					Sterile dressings (varied by treatment centre – details not given)	749	Varied based on routine local care.
Masters *et al* 2021	RCT	Patients undergoing surgery for hip fractures	Type of surgery, median age (>84 years)	120 days	PICO dressing	232	Applied according to surgeon's normal practice and the manufacturer's

Study	Study design	Surgical Procedure	Identified potential risk factors for surgical site infections	Study duration	Incisional dressings used	No. of Subjects	Treatment duration
		associated with trauma					instructions (up to 7 days of treatment).
					Sterile dressings (varied by treatment centre – details not given)	230	Varied based on routine local care.
Bueno-Lledo *et al* 2020	RCT	Patients undergoing incisional hernia repair	Obese patients undergoing incisional hernia repair (BMI > 30; total pop: n=37/150)	30 days	PICO dressing	72	Applied with an intentional duration of six days.
					Conventional sterile dressing (MEPORE pro; Molnlycke, Goteborg, Sweden)	74	Applied with an intentional duration of six days.
Andrianello *et al* 2020	RCT	Patients undergoing pancreatic resection	Type of surgery	90 days	PICO dressing	46	Applied with an intentional duration of seven days

Study	Study design	Surgical Procedure	Identified potential risk factors for surgical site infections	Study duration	Incisional dressings used	No. of Subjects	Treatment duration
					Sterile gauze until post-op day 3, then sterile island dressing (OPSITE Post-Op Visible; Smith & Nephew)	49	Dressing (OPSITE) was changed according to clinical judgement.

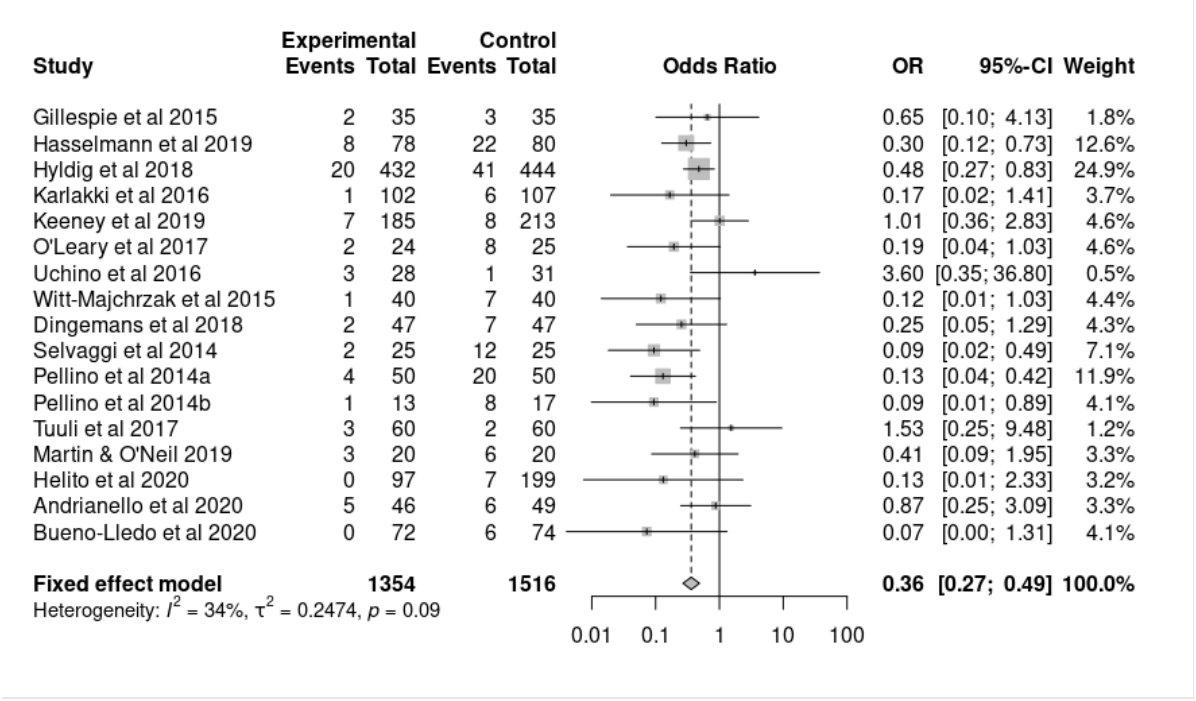
Together, the seventeen (17) studies contained 1,354 evaluable patients receiving the PICO Family (treatment group) and 1,516 patients receiving conventional wound dressings (control group). The conventional wound dressings used in each study can be seen in **Table 3** and ranged from standard transparent dressings to basic wound contact absorbent dressings. The endpoint in the studies was the incidence of infection in the treatment group compared to the control group, with follow-up of patients for at least 30 days following surgery as per CDC guidance. The treatment effect for each study was summarized using odds ratio (OR), which was calculated using the following formula: OR = AD/BC, where

- A = the number of subjects with Infection events for the treatment group
- B = the number of subjects without Infection events for the treatment group
- C = the number of subjects with Infection events for the control group
- D = the number of subjects without Infection events for the control group

An OR of less than 1 suggests a favorable effect by the treatment in reducing the incidence of infection in high risk patients, whereas an OR greater than 1 suggests a favorable effect by the conventional wound dressings. The 95% confidence interval (95% CI) for the odds ratio is calculated based on the standard error of Log(OR).

As demonstrated in **Figure 3**, there is an observable trend supporting a favorable effect by the PICO Family in reducing the incidence of infection compared to the control group.

Figure 3: Forest plot showing Infections in patients treated with PICO compared to SOC



Adverse events (AEs) or other potential device-related problems, ranging from patient reported noise concerns and vacuum failure to reports of pain and adverse skin reactions, were detailed in

fifteen (15) of the seventeen (17) studies included in the meta-analyses.

Literature Supports Reduction in Infection for Class I and II Wounds
To analyze the effect of the PICO Family on infection in wounds of different degrees of contamination, a wound classification designation was applied following the Center for Disease Control and Prevention (CDC) guidelines[24] .

Literature Support: Reduction in Superficial and Deep Surgical Site Infection (Infection Depth)
The definitions of "superficial" and "deep" incisional surgical site infections (SSIs) utilized within this analysis are based on the established and recognized definitions provided by the Centers for Disease Control and Prevention (CDC). According to the latest recommendations[24], superficial and deep incisional SSIs are briefly defined as follows:

- A superficial incisional SSI involves only skin and subcutaneous tissue of the incision and occurs within 30 days after any NHSN operative procedure.
- A deep incisional SSI involves deep soft tissues of the incision (for example, fascial and muscle layers) and occurs within 30 or 90 days after the NHSN operative procedure.

Meta-analysis of appropriate studies from Class I or Class II wound studies show a reduction in infection for superficial and deep infection when using the PICO Family compared to standard surgical dressing (SOC).. Specifically, to analyze the effect of the PICO Family on infections of different depths, subgroup analyses were performed using studies where the authors stated the use of the CDC criteria discussed above for superficial and deep SSIs[26].

Meta-analyses of the relevant studies show a statistically significant reduction in infection for both superficial and deep incisional infections for class I/II wounds when comparing use of the PICO Family to SOC (**Figures 4 and 5**). The meta-analysis for superficial SSI includes eight (8) studies (5 RCTs, 3 prospective observational) containing a total of 723 evaluable patients, of which 356 received the PICO Family (treatment group) and 367 received conventional wound dressings (control group). The deep SSI analysis includes six (6) studies (4 RCTs, 2 prospective observational) containing a total of 2,284 evaluable patients, of which 1,146 received the PICO Family (treatment group) and 1,138 received conventional wound dressings (control group). The conventional wound dressings used in each study can be found in **Table 3** and range from standard transparent dressings to simple adhesive plasters. The endpoint in the studies was the incidence of SSI (superficial and/or deep) in the treatment group compared to the control group.

Figure 4: Forest plot showing superficial SSI defined in patients treated with PICO Family compared to SOC

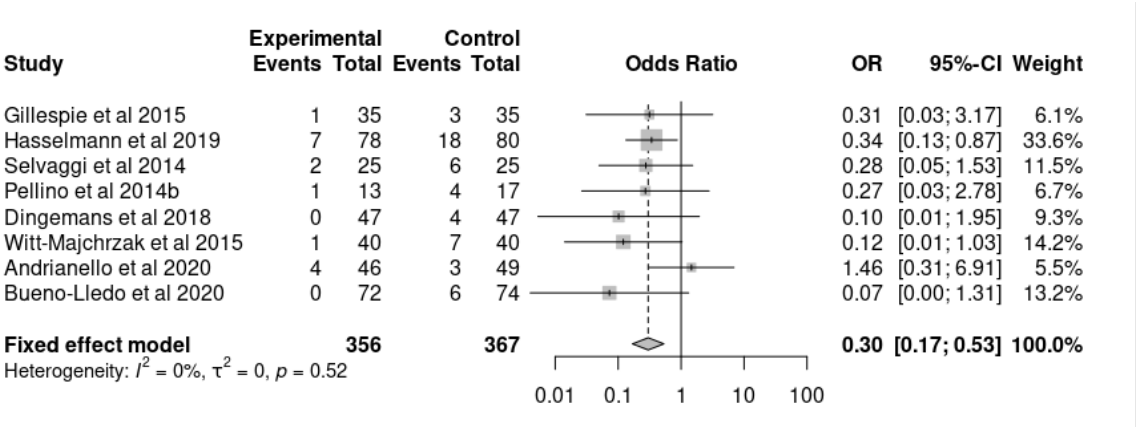
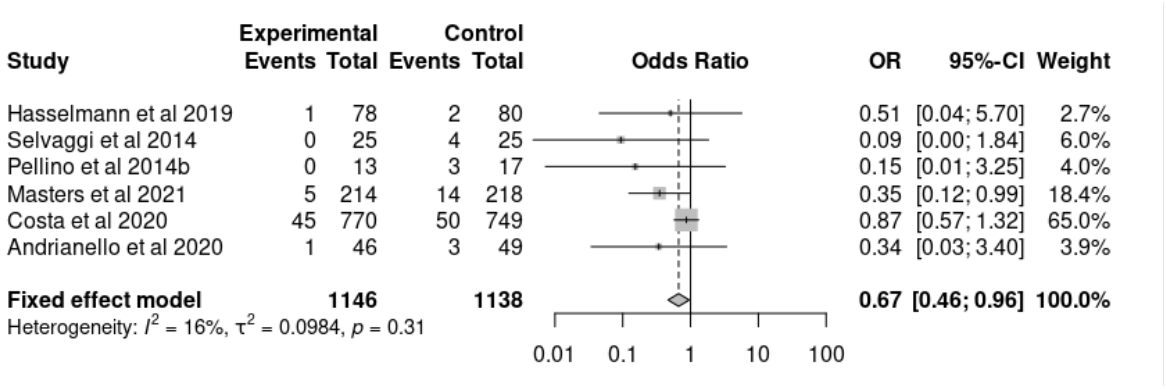


Figure 5: Forest plot showing deep SSI defined in patients treated with PICO Family compared to SOC



3. POST-OPERATIVE SEROMA

A review of literature is included to demonstrate that the PICO Family is intended to reduce the incidence of post-operative seroma for closed surgical incisions. Studies assessing seroma were only included if they had at least 10 days of follow-up time (see **Table 4**).

Literature Review

A meta-analysis of ten (10) studies demonstrated a statistically significant reduction in the odds of developing a seroma when using PICO in comparison to standard of care (SOC). Of the ten (10) prospective studies included in the meta-analysis for seroma:

- Seven (7) studies were randomized controlled trials and considered Level I evidence.
- Three (3) studies were considered Level II evidence, which are non-randomized prospective observational studies.

See **Table 4** below for a complete description of these studies.
The ten (10) studies contained 608 evaluable patients receiving the PICO Family (treatment group) and 618 patients receiving conventional wound dressings (control group). The conventional wound dressings used in each study can be found in **Table 4** and range from standard transparent dressings to basic wound contact absorbent dressings. The endpoint in the studies was the incidence of post-operative seroma in the treatment group compared to the control group for at least 10 days following surgery.

As demonstrated in **Figure 6**, there is an observable trend supporting a favorable effect by the PICO Family in reducing the incidence of seroma.

Table 4. Published Studies Evaluating Reduction in Seroma.

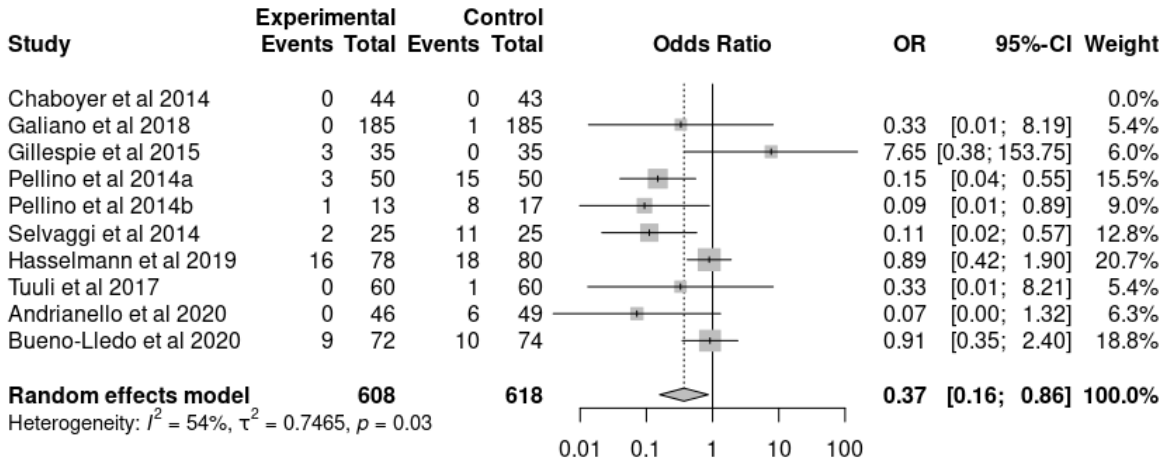
Study	Study design	Surgical Procedure	Follow up period	Incisional dressings used	No. of Subjects	Treatment duration
Chaboyer *et al* 2014	Randomized Controlled Trial (RCT)	Elective caesarean section patients	6 weeks	PICO dressing	44	4 days or more
				Comfeel dressing	43	Dressing was left on for 4 days, or longer if drainage continued, unless soiled or dislodged
Galiano *et al* 2018	RCT	Bilateral reduction mammoplasty patients	21 days (90 days)	PICO dressing	185	The overall duration of PICO treatment was a median of 7 days
				3M STERI-Strip (3M Health Care, St. Paul, Minn.).	185	Not reported
Gillespie *et al* 2015	RCT	Elective primary hip arthroplasty patients	6 weeks	PICO dressing	35	5 days
				Comfeel dressing reinforced with 2 absorbent dressings, and then with a self-adhesive, non-woven tape	35	Left intact and patients were discharged with their original dressing
Hasselmann *et al* 2019	RCT	Patients undergoing	90 days	PICO dressing	78	The PICO device and dressing was left in

Study	Study design	Surgical Procedure	Follow up period	Incisional dressings used	No. of Subjects	Treatment duration
		elective open vascular surgery with inguinal incisions				place for seven days post-operatively, after which patients were instructed to remove it.
				Vitri Pad (ViTri Medical, Saltsjo¨-Boo, Sweden or OPSITE Post-Op Visible; Smith and Nephew, London, UK)	80	The standard dressing was left in place for at least 48 hours, although changes due to moisture build-up was an issue on the standard dressing side and dressing changes did sometimes happen prior to 48 hours post-operatively.
Pellino *et al* 2014a	Prospective observational study	Patients (50 undergoing breast surgery, 50 colorectal surgery)	3 months	PICO dressing	50	7 days
				Basic wound contact absorbent dressings	50	Sterile removal for control after 48 h. On post-operative day 3, gauzes were removed sterilely and wounds left exposed if no complications occurred.
Pellino *et al* 2014b	Prospective observational	Crohn's disease patients	3 months	PICO dressing	13	7 days

Study	Study design	Surgical Procedure	Follow up period	Incisional dressings used	No. of Subjects	Treatment duration
		undergoing small bowel resection		Basic wound contact absorbent dressings	17	Sterile removal for control after 48 h. On post-operative day 3, gauzes were removed sterilely and wounds left exposed if no complications occurred.
Selvaggi *et al* 2014	Prospective observational study	Crohn's disease patients undergoing abdominal surgery	3 months	PICO dressing	25	7 days
				Basic wound contact absorbent dressings	25	Sterile removal for control after 48 h. On post-operative day 3, gauzes were removed sterilely and wounds left exposed if no complications occurred.
Tuuli *et al* 2017	RCT / Conference Abstract	Caesarean section patients	30 days	PICO dressing	60	Removed at discharge (usually on day 4)
				Standard wound dressing	60	The dressing was removed 24 to 48 hours
Bueno-Lledo *et al* 2020	RCT	Patients undergoing incisional hernia repair	30 days	Conventional sterile dressing (MEPORE pro; Molnlycke, Goteborg, Sweden)	74	Applied with an intentional duration of six days

Study	Study design	Surgical Procedure	Follow up period	Incisional dressings used	No. of Subjects	Treatment duration
				PICO dressing	72	Applied with an intentional duration of six days
Andrianello *et al* 2020	RCT	Patients undergoing pancreatic resection	90 days	Sterile gauze until post-op day 3, then sterile island dressing (OPSITE Post-Op Visible; Smith & Nephew)	49	Dressing (OPSITE) was changed according to clinical judgement.
				PICO dressing	46	Applied with an intentional duration of seven days

Figure 6: Forest plot showing Seroma in patients treated with PICO compared to SOC



Device related adverse events (AEs) or other potential device-related problems, ranging from sealing issues to reports of pain and adverse skin reactions, were reported in eight (8) of the ten (10) studies included in the meta-analysis.

4. DEHISCENCE

A review of literature is included to demonstrate that the PICO Family is intended to reduce the incidence of dehiscence in closed surgical incisions. Studies assessing dehiscence were only included if they had at least 10 days of follow-up time (see **Table 5**).

Literature Support

In accordance with the literature review process described above, seven (7) prospective studies demonstrated a statistically significant reduction in developing dehiscence when using PICO in comparison to standard of care. Of the seven (7) studies included in the meta-analysis for dehiscence:

- Six (6) studies were randomized controlled trials and considered Level I evidence.
- One (1) study was considered level II evidence, which are non-randomized prospective observational studies.

See **Table 5** below for a complete description of these studies.

The seven (7) studies contained 551 evaluable patients receiving the PICO Family (treatment group) and 656 patients receiving conventional wound dressings (control group). The conventional wound dressings used in each study can be found in **Table 5** and range from standard sterile dressings to fixation strips. The endpoint in the studies was the incidence of dehiscence in the treatment group compared to the control group for at least 10 days following surgery.

As demonstrated in **Figure 7**, there is an observable trend supporting a favorable effect by the PICO Family in reducing the incidence of dehiscence.

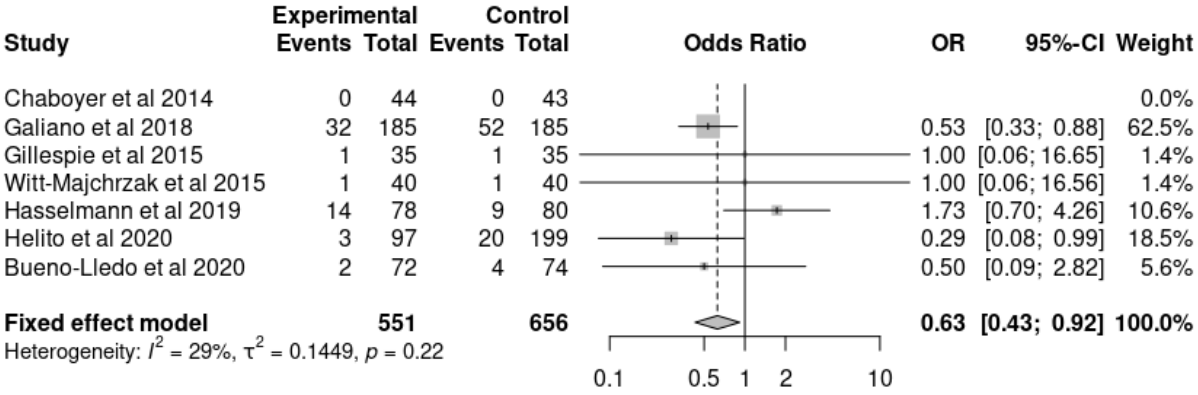
Table 5. Studies Evaluating Reduction in Dehiscence in Closed Surgical Incisions.

Study	Study design	Surgical Procedure	Follow up period	Incisional dressings used	No. of Subjects	Treatment duration
Chaboyer *et al* 2014	Randomized Controlled Trial (RCT)	Elective caesarean section patients	6 weeks	PICO dressing	44	4 days or more
				Comfeel dressing	43	Dressing was left on for 4 days, or longer if drainage continued, unless soiled or dislodged
Galiano *et al* 2018	RCT	Bilateral reduction mammoplasty patients	21 days (90 days)	PICO dressing or 3M STERI-Strip (3M Health Care, St. Paul, Minn.).	185	The overall duration of PICO treatment was a median of 7 days
					185	Not Reported
Gillespie *et al* 2015	RCT	Elective primary hip arthroplasty patients	6 weeks	PICO dressing or Comfeel dressing reinforced with 2 absorbent dressings, and then with a self-adhesive, non-woven tape	35	5 days
					35	Left intact and patients were discharged with their original dressing
					417	The dressing was left in situ for at least 24 hours
Witt-Majchrzak *et al* 2015	RCT	Patients undergoing coronary artery bypass grafting surgery	6 weeks	PICO dressing	40	Dressing changed on day 2 or 3 and on day 5 or 6 after surgery
				Conventional dressing	40	Dressings changed daily

Study	Study design	Surgical Procedure	Follow up period	Incisional dressings used	No. of Subjects	Treatment duration
Hasselmann *et al* 2019	RCT	Patients undergoing elective open vascular surgery with inguinal incisions	90 days	PICO dressing	78	The PICO device and dressing was left in place for seven days post-operatively, after which patients were instructed to remove it.
				(Vitri Pad; ViTri Medical, Saltsjo¨-Boo, Sweden or OPSITE Post-Op Visible; Smith and Nephew, London, UK)	80	The standard dressing was left in place for at least 48 hours, although changes due to moisture build-up was an issue on the standard dressing side and dressing changes did sometimes happen prior to 48 hours post-operatively.
				Sterile island dressing	20	Not Reported
Helito *et al* 2020	Prospective and historical controlled	Patients undergoing total knee arthroplasty	12 months	PICO dressing	97	Applied with an intentional duration of 7 days.
				Conventional surgical dressings	199	Applied with an intentional duration of 7 days.
Bueno-Lledo *et al* 2020	RCT	Patients undergoing incisional hernia repair	30 days	Conventional sterile dressing (MEPORE pro; Molnlycke, Goteborg, Sweden)	74	Applied with an intentional duration of six days

Study	Study design	Surgical Procedure	Follow up period	Incisional dressings used	No. of Subjects	Treatment duration
				PICO dressing	72	Applied with an intentional duration of six days

Figure 7: Forest plot showing dehiscence in patients treated with PICO compared to SOC



Device related adverse events (AEs) or other potential device-related problems, ranging from sealing issues to reports of pain and adverse skin reactions, were reported in five (5) of the seven (7) studies included in the meta-analysis.

5. LIMITATIONS OF THE CLINICAL EVIDENCE

There can be many inherent limitations to meta-analyses, such as publication bias, selection bias, and varying quality of the underlying studies. Efforts were made in the study identification and selection process to reduce potential biases by selecting higher quality level I and level II studies. The criteria used to assess quality within the identified studies is detailed earlier in the methodology of the systematic literature review (**Section 1** and **Table 2**). Another potential bias affecting studies included in meta-analyses is publication bias, whereby studies with statistically significant results are more likely to be published. This may also occur in the context of selective outcome reporting in which only significant outcomes are reported at study publication. To address this, searches were also conducted on ClinicalTrials.gov to check for completed trials with results available that had not been published.

Most studies (16/25) included in the systematic literature review were at higher risk of bias or the risk for bias was unclear. Specifically, many level I studies failed to include an intention to treat (ITT) analysis and often only reported on the per protocol (PP) analysis. Deficiencies in level II prospective observational studies included a lack of reporting of confidence intervals or p-values. Additional sources of bias included the variability between studies in the length of follow-up time for assessment of surgical site complications such as SSI. While inclusion for analysis required a follow-up period of at least 30 days post-operatively (as per CDC definitions), some studies exceeded this threshold sometimes by a few weeks. As a result, this may have impacted on the number of detected SSIs during the specified clinical endpoint. Some studies (Van der Valk *et al* 2017; Dingemans *et al* 2018; Helito *et al* 2020) included in the analysis used a historical cohort

group as the control arm. There can be problems with interpreting data based on historical comparators. Namely, clinical practice, such as the use of technologies, procedures or care pathways, may have changed over time since the original data was collected meaning that any clinical improvement in the intervention arm may be attributable to these medical advances, rather than just the intervention alone. The systematic literature review also only included studies published in the English language. As such, there is the possibility of excluding valid data published in a different language.

Although these limitations should be considered when examining the results from these meta-analyses, the depth and breadth of the evidence provided gives reassurance to the conclusions reached for each of the outcomes assessed for the proposed Indications For Use. In addition, by the very nature of the inclusion criteria used for the systematic literature review, only studies considered methodologically robust (i.e., prospective and comparative) were selected for these analyses.

The device has not been demonstrated to be effective in reducing the incidence of surgical site infection, seroma, and dehiscence in all surgical procedures and patient populations; therefore, the device may not be recommended for routine use to reduce surgical site infection, seroma, and dehiscence. Surgeons should continue to follow the 'Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection'[31] and the 'American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines'[25] for best practices in preventing surgical site infection.

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21 CFR 807.92 (b)(3): Conclusions drawn

Based on the clinical and non-clinical supporting information provided in this submission, the subject device is substantially equivalent to the legally marketed predicate device (PREVENA). To the extent that there are differences between the subject device and the predicate, these differences do not raise new or different questions of safety or effectiveness.