

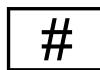
AxiUS™

- (EN)** INSTRUMENT PROTECTION SYSTEMS INSTRUCTIONS FOR USE
- (FR)** SYSTÈMES DE PROTECTION DES INSTRUMENTS MODE D'EMPLOI
- (DE)** INSTRUMENTENSCHUTZSYSTEME GEBRAUCHSANWEISUNG
- (IT)** SISTEMA DI PROTEZIONE STRUMENTI ISTRUZIONI PER L'USO
- (ES)** SISTEMAS DE PROTECCIÓN DE INSTRUMENTAL INSTRUCCIONES DE USO
- (PT-BR)** SISTEMAS DE PROTEÇÃO DE INSTRUMENTOS INSTRUÇÕES DE USO
- (NL)** INSTRUMENTBESCHERMINGSSYSTEMEN GEBRUIKSAANWIJZING
- (SV)** INSTRUMENTSKYDDSSYSTEM ANVÄNDARINSTRUKTIONER
- (DA)** INSTRUMENTBESKYTTELSESYSTEMER BRUGSANVISNING
- (FI)** INSTRUMENTTIEN SUOJAUSJÄRJESTELMÄT KÄYTTÖOHJEET
- (EL)** ΣΥΣΤΗΜΑΤΑ ΠΡΟΣΤΑΣΙΑΣ ΟΡΓΑΝΩΝ ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ
- (PL)** SYSTEMY OCHRONY NARZĘDZI INSTRUKCJA UŻYTKOWANIA
- (TR)** ALET KORUMA SİSTEMLERİ KULLANMA TALİMATLARI
- (RU)** СИСТЕМЫ ЗАЩИТЫ ИНСТРУМЕНТОВ ИНСТРУКЦИЯ ПО ЭКСПЛУАТАЦИИ
- (CS)** SYSTÉMY OCHRANY NÁSTROJŮ NÁVOD K POUŽITÍ
- (HU)** MŰSZERVÉDŐ RENDSZEREK HASZNÁLATI ÚTMUTATÓ
- (SK)** SYSTÉMY NA OCHRANU PRÍSTROJOV POKYNY NA POUŽITIE
- (NO)** SYSTEMER FOR INSTRUMENTBESKYTTELSE BRUKSANVISNING
- (SL)** SISTEMI ZA ZAŠČITO INSTRUMENTOV NAVODILA ZA UPORABO
- (BG)** СИСТЕМИ ЗА ЗАЩИТА НА ИНСТРУМЕНТИ ИНСТРУКЦИИ ЗА УПОТРЕБА
- (RO)** SISTEME DE PROTECȚIE A INSTRUMENTELOR INSTRUCȚIUNI DE UTILIZARE
- (ET)** INSTRUMENTIDE KAITSESÜSTEEMID KASUTUSJUHEND
- (LV)** INSTRUMENTU AIZSARDZĪBAS SISTĒMU LIETOŠANAS INSTRUKCIJA
- (HR)** SUSTAV ZA ZAŠTITU INSTRUMENATA UPUTE ZA UPOTREBU
- (SR)** SISTEMI ZAŠTITE INSTRUMENATA UPUTSTVO ZA UPOTREBU
- (LT)** INSTRUMENTŲ APSAUGOS SISTEMŲ NAUDOJIMO INSTRUKCIJA
- (ZH-CN)** 器械保护系统使用说明书
- (ZH)** 器械保護系統使用說明書
- (KO)** 기기 보호 시스템 사용 지침
- (JA)** 器具保護システム 使用説明書

For the full instructions for use visit:
Pour le mode d'emploi complet, visitez le site :
Die vollständige Gebrauchsanweisung finden Sie unter:
Per le istruzioni per l'uso complete, visitare:
Para ver las instrucciones completas de uso, visite:
Para as instruções completas de utilização visite:
Ga voor de volledige gebruiksaanwijzing naar:
För att få tillgång till hela bruksanvisningen, besök:
Se hele brugsanvisningen her:
Täydelliset käyttöohjeet ovat osoitteessa:
Για πλήρεις οδηγίες χρήσης, επισκεφτείτε:
Pełną instrukcję użytkowania można znaleźć na stronie:
Kullanma talimatlarının tamamı için şu adresi ziyaret edin:
Для получения полной инструкции по эксплуатации посетите:
Pro úplný návod k použití navštivte:
A teljes használati utasításért látogasson el ide:
Úplné pokyny na použitie nájdete na:
For en komplett bruksanvisning, gå til:
Za celotna navodila obiščite:
За пълните инструкции за употреба посетете:
Pentru instrucțiunile de utilizare complete, accesați:
Täieliku kasutusjuhendi leiate aadressilt:
Lietošanas instrukcijas pilna versija ir pieejama šajā tīmekļa vietnē:
Potpune upute za upotrebu pronađite pod:
Kompletna uputstva potražite na adresi:
Išsamią naudojimo instrukciją rasite:
有关完整的使用说明，请访问：
有關完整的使用說明，請瀏覽：
전체 사용 지침은 다음 사이트를 방문하십시오.
使用説明書の詳細については、以下をご覧ください。



summitmedicalusa.com/ifus



IFU-40192-03

If you have any questions, please contact our customer service representatives at **1.888.229.2875**. / Pour toute question, veuillez contacter nos représentants du service clientèle au **1.888.229.2875**. / Wenn Sie Fragen haben, wenden Sie sich an unseren Kundendienst unter **1.888.229.2875**. / In caso di domanda, contattare gli addetti all'assistenza clienti al numero **1.888.229.2875**. / Si tiene alguna pregunta, póngase en contacto con nuestros representantes del servicio de atención al cliente llamando al **1.888.229.2875**. / Se você tiver alguma dúvida, entre em contato com nossos representantes de atendimento ao cliente pelo telefone **1.888.229.2875**. / Neem voor eventuele vragen contact op met onze klantenservice via **1.888.229.2875**. / Om du har frågor, var god kontakta våra kundtjänstrepresentanter på telefon **+1.888.229.2875**. / Hvis du har spørgsmål, bedes du kontakte vores kundeservicerepræsentanter på **1.888.229.2875**. / Jos sinulla on kysyttävää, ota yhteyttä asiakaspalveluumme puhelinnumerossa **1.888.229.2875**. / Αν έχετε τυχόν ερωτήσεις, επικοινωνήστε με τους αντιπροσώπους της εξυπηρέτησης πελατών μας στο **1.888.229.2875**. / Wszelkie pytania należy kierować do przedstawicieli działu obsługi klienta pod numerem telefonu **1.888.229.2875**. / Herhangi bir sorunuz varsa, lütfen şu numaradan müşteri hizmetleri temsilcilerimizi arayın: **1.888.229.2875**. / Если у вас есть какие-либо вопросы, свяжитесь с представителями нашей службы поддержки клиентов по телефону **1.888.229.2875**. / Máte-li nějaké dotazy, obraťte se na naše zástupce služeb pro zákazníky na čísle **1.888.229.2875**. / Ha bármilyen kérdése van, kérjük, vegye fel a kapcsolatot ügyfélszolgálati képviselőinkkel az **1.888.229.2875** telefonszámon. / Ak máte akékoľvek otázky, obráťte sa na našich zástupcov zákazníckeho servisu na čísle **1.888.229.2875**. / Hvis du har noen spørsmål, ta kontakt med våre kundeservicerepresentanter på **1.888.229.2875**. / Če imate kakršna koli vprašanja, se obrnite na naše predstavnike službe za stranke na **1-888-229-2875**. / Ако имате някакви въпроси, моля, свържете се с нашите представители за обслужване на клиенти на **1.888.229.2875**. / Dacă aveți întrebări, vă rugăm să contactați reprezentanții departamentului nostru de relații clienți la **1.888.229.2875**. / Küsimuste korral võtke ühendust meie klienditeenindusega numbril **1.888.229.2875**. / Ja rodas jautājumi, lūdzu, sazinieties ar mūsu klientu apkalpošanas nodaļas pārstāvjiem pa tālruni **1.888.229.2875**. / Ako imate bilo kakva pitanja, nazovite predstavnika naše korisničke službe na **1.888.229.2875**. / Ako imate pitanja, obratite se predstavnicima korisničke podrške na **1.888.229.2875**. / Jei turite klausimų, susisiekite su mūsų klientų aptarnavimo atstovais telefonu **1 888 229 2875**. / 如有任何疑问，请致电**1.888.229.2875**与我们的客户服务代表联系。 / 如有任何疑問，請撥打電話 **1.888.229.2875** 與我們的客戶服務代表聯絡。 / 질문이 있는 경우 **1.888.229.2875**의 당사 고객 서비스 대표번호로 문의하십시오. / ご不明な点がございましたら、以下のカスタマーサービス担当者までお問い合わせください。 **1.888.229.2875**

- EN** Request a printed instructions for use manual at no cost that arrives within 7 days of request confirmation.
- FR** Vous pouvez demander un mode d'emploi imprimé gratuit, qui vous sera adressé dans les 7 jours suivant la confirmation de la demande.
- DE** Fordern Sie gratis eine gedruckte Version der Gebrauchsanweisung an; diese wird Ihnen innerhalb von 7 Tagen nach Eingang Ihrer Anfrage zugestellt.
- IT** Richiedere un manuale stampato gratuito contenente le istruzioni per l'uso che arriverà entro 7 giorni dalla conferma della richiesta.
- ES** Solicitar un manual de instrucciones de uso impreso sin coste que llegará en los 7 días posteriores a la confirmación de la solicitud.
- PT-BR** Solicite um manual de instruções de uso impresso sem custo que chega em até 7 dias após a confirmação do pedido.
- NL** Vraag gratis deze handleiding op papier. U ontvangt deze binnen 7 dagen na bevestiging van uw aanvraag.
- SV** Begär användarinstruktioner på papper som kommer kostnadsfritt inom 7 dagar efter bekräftad förfrågan.
- DA** Bed om en gratis trykt version af brugsanvisningen, som vil ankomme inden for 7 dage fra bekræftelsen af anmodningen.
- FI** Pyydä tulostetut käyttöohjeet ilmaiseksi, saat ne 7 päivän kuluessa tilauksen vahvistuksesta.
- EL** Ζητήστε ένα έντυπο εγχειρίδιο οδηγιών χρήσης χωρίς χρέωση που θα το λάβετε εντός 7 ημερών από την αίτηση Επιβεβαίωση.
- PL** Fizyczna instrukcja obsługi dostępna jest bezpłatnie, na życzenie. Zostanie dostarczona w przeciągu 7 dni od potwierdzenia zgłoszenia.
- TR** İsteğin onaylanmasıyla 7 gün içerisinde ulaşan basılı bir kullanma kılavuzunu ücretsiz olarak isteyin.
- RU** Закажите бесплатно печатную версию инструкции по эксплуатации, которая будет доставлена в течение семи дней с момента подтверждения заявки.
- CS** Požádejte o vytištěný návod k použití, který zdarma dorazí během 7 dní od potvrzení žádosti.
- HU** Igényeljen ingyenesen nyomtatott használati útmutatót, amelyet a kérés visszaigazolásától számított 7 napon belül kézhez kap.
- SK** Požiadajte o bezplatné doručenie tlačeného návodu na použitie, ktorý vám bude doručený do 7 dní od potvrdenia žiadosti.
- NO** Be om en kostnadsfri, trykt bruksanvisning som ankommer innen sju dager etter at forespørselen blir bekreftet.
- SL** Zahtevajte brezplačna tiskana navodila za uporabo, ki prispejo v 7 dneh po potrditvi zahteve.
- BG** Поискайте безплатно отпечатано ръководство с инструкции за употреба, което ще пристигне в срок от 7 дни след потвърждаване на заявката.
- RO** Solicitați gratuit un manual cu instrucțiuni de utilizare pe suport de hârtie, pe care-l veți primi în termen de 7 zile de la confirmarea solicitării.
- ET** Prinditud kasutusjuhendi tasuta tellimisel saabub see 7 päeva jooksul pärast tellimuse kinnitamist.
- LV** Pieprasiet izdrukātos norādījumus lietošanas rokasgrāmatai bez maksas, kas tiks piegādāti 7 dienu laikā pēc pieprasījuma.
- HR** Zatražite besplatni ispisani priručnik s uputama za upotrebu koji će stići na vašu adresu u roku od 7 dana od potvrde zahtjeva.
- SR** Zatražite besplatni štampani priručnik sa uputstvima za upotrebu koji stiže u roku od 7 dana od potvrde zahteva.
- LT** Užsisakykite spausdintą naudojimo instrukciją, kuri bus nemokamai pristatyta per 7 dienas nuo prašymo patvirtinimo.
- ZH-CN** 索取一份免费的印刷版使用说明书，将在要求确认后7天内送达。
- ZH** 索取一份免費的列印版使用說明書，將在要求確認後 7 天內送達。
- KO** 요청 확인 후 7일 이내에 도착하는 인쇄된 사용 지침을 무료로 요청하십시오.
- JA** 使用説明書（ペーパー版）を請求すると無料で提供され、請求確認後7日以内に到着するように手配されます。



summitmedicalusa.com/contact/



The instructions provided within have been validated by the device manufacturer as being capable of reprocessing reusable medical devices.

Individual sterilizers, instrument cleanliness, specific loading of instrument trays, types and geometry of instruments, sterilization containers, filters, and wrappings vary at each location.

READ THIS SECTION BEFORE PLACING PRODUCT INTO SERVICE

INTENDED USE/INDICATIONS FOR USE SUMMARY

The InstruSafe® Instrument Protection Systems cassettes/trays are intended to contain and protect reusable medical devices during transport, sterilization, and storage. InstruSafe® Instrument Protection System cassettes/trays are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes/trays are intended to allow sterilization of the enclosed medical devices during these sterilization cycles:

- Pre-Vacuum Steam (ISO 17665-1 and EN 285)

The InstruSafe Instrument Protection System cassettes/trays are not intended on their own to maintain sterility. The InstruSafe Instrument Protection System cassettes/trays are intended to be used in conjunction with a legally marketed wrap.

A full list of device models is provided in Appendix A, which can be viewed at www.instrusafe.com/ifus.

DEVICE DESCRIPTION

Summit Medical InstruSafe Instrument Protection Systems are cassettes/trays used to enclose and hold surgical instruments and instrument accessories in an organized manner during the sterilization process and subsequent storage and transportation. The cassettes/trays do not have direct patient contact. The cassettes/trays by themselves do not maintain sterility. The cassettes/trays are different sizes of the same basic configuration: a rectangular base with latchable cover. The cassettes/trays have perforations to allow sterilant penetration. The cassettes/trays contain silicone inserts in the base and/or cover to hold, organize, and protect the surgical instruments within the cassette/tray during the sterilization process and subsequent storage and transportation.

INTENDED USER

The InstruSafe® Instrument Protection Systems are intended to be used by healthcare professionals in the operating room and sterile processing department for transportation, sterilization, and storage of medical devices.

LIMITATION ON PROCESSING

1. The end of useful life on the InstruSafe Instrument Protection System is a minimum of 25 sterilization cycles. Inspect the tray before use for wear and damage caused by use. Discontinue use if visible signs of wear are present, including corrosion, mechanical failures, cracking, peeling, flaking, broken welds, damaged feet, damaged latches, damaged Hold-Its®/Hold-Downs, discoloration, etc.
2. See **Table 2** for sterilization methods and configurations.
3. **DO NOT OVERLOAD** InstruSafe Systems or components.
4. **DO NOT OVERLOAD** individual Hold-Its slots. Load only one instrument per Hold-Its slot.
5. Inside of sterilizers, **DO NOT STACK** individually wrapped InstruSafe Systems or components. Separate wrapped InstruSafe Systems or components from each other or any other items on separate shelves of the sterilizer to allow for maximum sterilant flow.
6. The use of non absorbent tray liners (e.g. silicone fingered organizing mat) can cause condensate to pool. If visible moisture is present, re-sterilize with a longer dry time.
7. The total weight of the system (e.g. tray, and instrument load) must not exceed 25 pounds (11.34 kg).
8. Instruments (e.g. endoscopes and instruments with lumens or channels) should be prepared and sterilized according to the instrument manufacturer's instructions.
9. Consult sterilizer manufacturer's instructions for use for additional limitations (e.g. dimensional or weight constraints).

WARNINGS

- For aluminum InstruSafe Systems, use only neutral pH (6.0 – 8.5) detergents to avoid damaging the finish. A detergent with a highly acidic or highly alkaline pH could permanently damage the anodized aluminum finish of the cassette and metal components.
- Do not use if package is damaged or unintentionally opened prior to use.

Note: Clean and inspect cassettes according to the instructions provided prior to placing into service.

UNIVERSAL PRECAUTIONS

- Personnel should wear all personal protective clothing and equipment as required by their employer's/department's operating procedures for the contamination level they will be exposed to.
- Keep dissimilar metals separated during sterilization to prevent corrosion.

POINT OF USE

Remove gross soil with disposable cloth/paper wipe. Contaminated components should be kept moist until qualified cleaning processes can be applied.

CLEANING

Refer to the instrument manufacturer’s instructions for use for specific instructions for cleaning the instruments in the cassettes.

Use one of the following validated cleaning options to clean the cassette/tray is recommended.

Use only neutral pH (6.0 – 8.5) solutions free of sodium carbonate to avoid damaging finish for aluminum cassettes.

DO NOT use scouring pads or abrasive cleaners. **DO NOT** store cassette in liquid.

1. Manual Gross Decontamination:

- A. Materials needed: Neutral pH (6.0 – 8.5) enzymatic detergent, soft bristle brush, and running water.
- B. Remove all visible soil and contaminants using a soft bristle brush. The entire cassette should be immersed while cleaning, to aid in the removal of contaminants and to reduce splashing of detergent on personnel, for a minimum of 2 minutes.
- C. Rinse thoroughly for a minimum of 1 minute with clean water to remove all detergent. See rinsing instructions on the detergent label.

2. Ultrasonic Clean:

- A. Prepare enzyme wash in an ultrasonic cleaning unit.
- B. Place a single cassette in the detergent and run for a minimum of ten minutes.
- C. Rinse for a minimum of 2 minutes with cold tap water.
- D. Visually inspect cassette for contaminants. Repeat the cycle if necessary to remove visible contamination.

3. Automated Washer:

The InstruSafe Instrument Protection Systems have been validated for the automatic wash system cycle listed in **Table 1**. Qualification of specific parameters will need to be conducted by the processor.

Table 1

CYCLE	WATER TEMPERATURE	CLEANING PROCESS
Pre-Wash 1 & 2	Cold Tap Water	Re-Circulation Time: 2 Minutes
Enzyme Wash	Hot Tap Water	Soaking Time: 4 Minutes
Wash 1	Heated at 150°F (65.5°C)	Re-Circulation Time: 15 Minutes
Rinse 1 & 2	Hot Tap Water	Re-Circulation Time: 5 Minutes

Note: After completion of an automatic wash cycle, visually inspect the InstruSafe System (cassette and accessories) for any remaining visible soil. All visible soil must be removed by hand cleaning, brushing, ultrasonic, or additional automatic cycles prior to sending to sterilization.

DISINFECTION

InstruSafe systems are intended to be terminally sterilized.

MAINTENANCE, INSPECTION, AND TESTING

InstruSafe systems may be reused until unacceptable deterioration such as corrosion, cracking, rust, peeling, flaking, discoloration, or mechanical failure occurs.

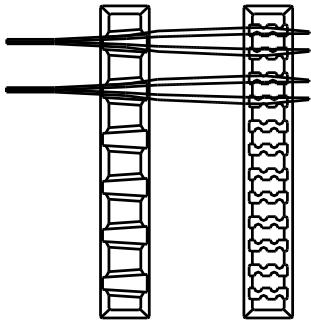
Signs of Mechanical Failure Include:

- Broken or cracked corners or welds
- Broken or non-working latches
- Missing, torn, or cut silicone inserts
- Missing or damaged feet

ASSEMBLY

1. Place the instruments in the predetermined holders or area defined by the locating posts so that all instrument surfaces will be exposed to sterilant. See **Figure A**. Be sure that only one instrument is in each slot. When possible, disassemble or open all parts of the instrumentation per the instrument manufacturer’s instructions.
DO NOT overload holders or exceed weight limits of cassettes. See Appendix A.

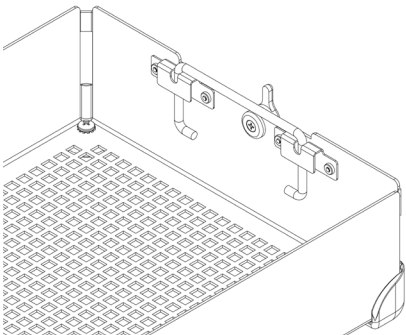
Figure A.



Note: Instruments (e.g. endoscopes and instruments with lumens or channels) should be prepared and sterilized according to the instrument manufacturer’s instructions for use.

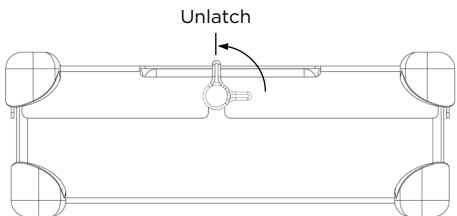
2. Ensure that handles are positioned inside the cassette (retracted position). Shown in **Figure B**.

Figure B.



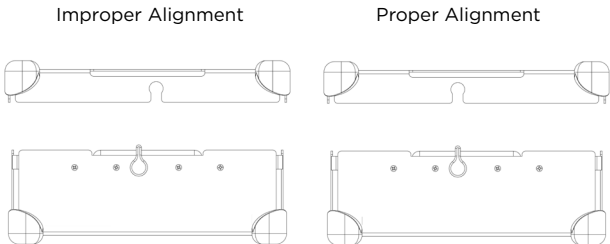
3. Place the cassette cover on the cassette base ensuring that the latches are properly positioned with the latch slot on the cassette cover, then close the latches. See **Figure C**.

Figure C.



Note: The latches are offset so that the cassette cover always aligns properly with the base. This ensures that the holders are aligned when the cover is secured. See **Figure D** for proper alignment.
DO NOT force the cassette cover onto the cassette base as it may damage instruments and the cassette.

Figure D.



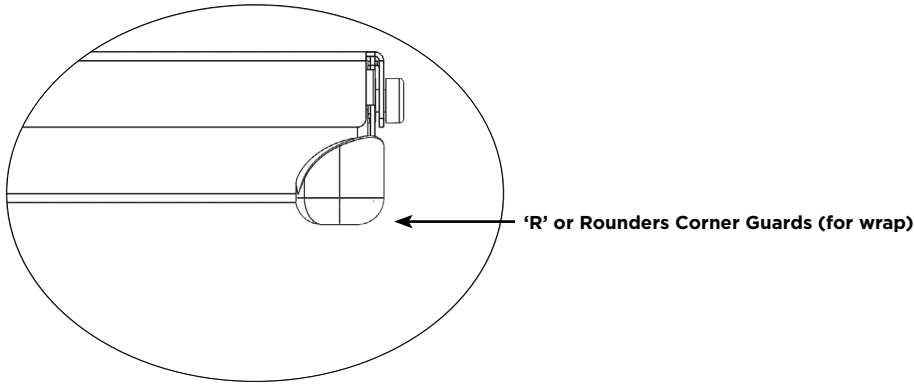
PACKAGING

InstruSafe Systems may be wrapped with a legally marketed wrap. Refer to the Indications for Use statements found in the instructions for use.

Using with Wrap:

- 1. Before wrapping the cassette, ensure it has the proper foot style. R should be used with wrap. See **Figure F**.

Figure F.



- 2. Wrap the cassette using legally marketed wrap per the wrap manufacturer’s instructions.
- 3. Sterilize the pack using one of the sterilization cycles listed in the instructions for use.

STERILIZATION

See **Table 2** for sterilization parameters that have been qualified for the sterilization of InstruSafe Systems.

Note: These sterilization methods and cycles are validated for the tray only. Refer to FlexDex Surgical® AXIUS™ IFU for validated methods for the AXIUS™ device.

Table 2.

STERILIZATION METHOD	CYCLE (times)
Pre-Vacuum Steam	Parameter: Temperature 270°F (132°C) Expose Time 4 minutes Dry Time 30 minutes

Summit Medical has validated the following sterilization methods:

- The 4 minute autoclave sterilization cycle in legally marketed wrap.

DO NOT exceed the load capacity of the sterile container as specified by the manufacturer.

Please consult the sterilizer instruction manual to ensure intended loads are compatible with the intended sterilization cycle.

INDICATIONS FOR USE

4 Minute Steam, Wrap

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycle. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility.

Autoclave Sterilization Parameter	
Cycle	Pre-Vacuum
Temperature	270°F (132°C)
Exposure Time	4 minutes
Minimum Dry Time	30 minutes
*Validated by Summit Medical for use in Pre-Vacuum Steam sterilizers ONLY operating at 270°F (132°C) for 4 minutes exposure time. Consult container instructions to ensure that contents do not exceed the sterilization container's intended load claims.	

STORAGE

Store terminally sterile cassettes that are wrapped on storage shelf in a horizontal position. Consult wrap manufacturer for shelf life information.

DISPOSAL

In the event the InstruSafe® Instrument Protection Systems do not pass inspection prior to use or have otherwise been deemed no longer fit for purpose, the devices shall be disposed of in line with local protocol. The method of disposal shall depend on the potential risks of cross-contamination and infection when the need for disposal is identified.

SERIOUS INCIDENT REPORTING

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the FDA/competent authority of the Member State in which the user and/or patient is established.

WARRANTY

LIMITED WARRANTY FOR SUMMIT MEDICAL INSTRUSAFE INSTRUMENT PROTECTION SYSTEM.

THIS LIMITED WARRANTY AND THE REMEDY PROVIDED HEREIN ARE EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES AND, UNLESS STATED HERE-IN, ANY STATEMENTS OR REPRESENTATIONS MADE BY ANY OTHER PERSON OR FIRM ARE VOID. THE DURATION OF ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE SHALL BE LIMITED TO THE DURATION OF THE EXPRESS LIMITED WARRANTY. NEITHER SUMMIT MEDICAL NOR ITS AFFILIATES SHALL BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL LOSSES OR DAMAGES, RESULTING FROM THE USE OR INABILITY TO USE THE INSTRUSAFE SYSTEM, WHETHER RESULTING FROM BREACH OF WARRANTY OR ANY OTHER LEGAL THEORY.

This Limited Warranty gives you specific legal rights, and you may also have other rights which vary from State to State. Some States do not allow limitations on how long an implied warranty lasts, or do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusions may not apply to you.

What Is Covered. Summit Medical warrants the original purchaser that the InstruSafe system enclosed with this Limited Warranty conforms to the manufacturer's specifications and is free from defects in workmanship and material for a period of 12 months from the date of original purchase. If the original purchaser transfers the InstruSafe System to another party, this Limited Warranty will not be enforceable by the party to whom the product is transferred.

What We Will Do To Correct Problems. Should your InstruSafe System prove defective during this period, you must notify Summit Medical or an authorized distributor or dealer of Summit Medical. You must permit Summit Medical or its representatives to make such investigation, examination and tests as Summit Medical deems appropriate and, if requested to do so, you will return the product to the factory at the address set forth below. Summit Medical's sole obligation under this Limited Warranty is, at its option, to repair or replace the defective product or products, without charge for parts or labor. Postage, insurance or shipping costs incurred in presenting your InstruSafe System product for warranty service are your responsibility.

What Is Not Covered. This Limited Warranty is contingent upon proper use and maintenance of the product; it does not cover products that have been improperly shipped, or that have been misused, abused, neglected, or improperly maintained, cleaned or stored, or that have been serviced other than by Summit Medical or an authorized distributor or dealer of Summit Medical or that have been modified without the express approval of Summit Medical. Failure to follow the directions in the owner's manual may constitute improper use or maintenance of the product and causes this Limited Warranty not to apply. This Warranty does not extend to normal wear or to replacement items.

If you have questions or claims related to this warranty, contact:

Customer Service Department
Summit Medical
815 Vikings Parkway, Suite 100
St. Paul, MN 55121 | USA
www.instrusafe.com

PHONE: 651-789-3939 | 888-229-2875
FAX: 651-789-3979 | 888-229-1941
EMAIL: customerservice@innoviamedical.com

Symbol Reference Key / Légende des symboles / Symbollegende / Legenda dei simboli / Clave de referencia de los símbolos / Chave de referência de símbolo / Legenda / Symbol Referensnyckel / Symbolreferencenøgle / Symbolien merkitys / Υπόμνημα συμβόλων / Objaśnienie symboli / Simge Referans Anahtarı / Расшифровка символов / Použité symboly / Szimbólumok magyarázata / Referenčný klúč k symbolom / Symbolreferansenøkkel / Referenčni ključ simbola / Легенда на символите / Tastá simbol de referință / Sûmbolite legend / Simbolu skaidrojums / Referentni ključ simbola / Legenda simbola / Simbolių paaiškinimas / 符号参考图例 / 符號參考圖例 / 기호 참조 키 / 記号参照キー	
	Consult instructions for use / Consulter les recommandations d'utilisation / Gebrauchsanweisung beachten / Consultare le istruzioni per l'uso / Consulte las instrucciones de uso / Consulte as instruções de uso / Raadpleeg de gebruiksaanwijzing / Se bruksanvisningen / Se bruksanvisning / Lue käyttöohjeet / Συμβουλευθείτε τις οδηγίες χρήσης / Należy zapoznać się z instrukcją obsługi / Kullanim talimatlarını bakın / См. инструкции по эксплуатации / Prečtete si návod k použití / Tekintse át a használati útmutatót / Pozrite návod na použitie / Se bruksanvisning / Preglejte navodila za uporabo / Направете справка в инструкциите за употреба / Consultați instrucțiunile de utilizare / Vaadake kasutusjuhendit / Skatīt lietošanas instrukciju / Pročitati upute za uporabu / Pogledajte uputstvo za upotrebu / Žr. naudojimo instrukciją / 请参阅使用说明书 / 사용 지침 참조 / 使用説明書を参照してください
	Quantity / Quantité / Stückzahl / Quantità / Cantidad / Quantidade / Aantal / Antal / Antal / Määrä / Ποσότητα / Ilość / Miktar / Количество / Množství / Mennyiség / Množstvo / Mengde / Količina / Количество / Cantitate / Kogus / Daudzums / Količina / Kiekis / 量 / 數量 / 수량 / 数量
	Non-sterile / Non stérile / Unsteril / Non sterile / No estéril / Não esterilizado / Niet-steriel / Ikke-steril / IKKE-STERIL / Ei steriili / Μη αποστειρωμένο / Niesterylny / Steril deșgildir / Нестерильно / Nesterilini / Nem steril / Nesterilné / Ikke steril / Nesterilino / Нестерильно / Nesterile / Mittesteriiline / Nesterilis / Nesterilno / Nesterilino / Nesterilu / 非灭菌 / 비-멸균 / 非滅菌
	Catalogue number / Numéro de catalogue / Artikelnummer / Numero di catalogo / Número de catálogo / Número de catálogo / Catalogusnummer / Katalognummer / Katalognummer / Luettelonumero / Αριθμός καταλόγου / Numer katalogowy / Katalog Numarasi / Номер по каталогу / Katalogové číslo / Katalógus szám / Katalogové číslo / Katalognummer / Kataloška številka / Kataloženomer / Numărul de catalog / Kataloogi number / Kataloga numurs / Kataloški broj / Kataloški broj / Katalogo numeris / 目錄號 / 카탈로그 번호 / カタログ番号
	Batch Code / Code de lot / Chargennummer / Codice lotto / Código de lote / Código do lote / Batchcode / Satsnummer / Partikode / Eränumero / Κωδικός παρτίδας / Kod partii / Parti Kodu / Код партии / Kód šarže / Tételkód / Partikode / Koda serije / Код на партида / Cod lot / Partii kood / Sērijas numurs / Šifra serije / Kód serije / Partijos kodas / 批号 / 批號 / 배치 코드 / バッチコード
	Date of Manufacture / Date de fabrication / Herstellungsdatum / Data di produzione / Fecha de fabricación / Data de fabricaço / Productiedatum / Tillverkningsdatum / Fremstillingsdato / Valmistuspäivä / Ημερομηνία κατασκευής / Data produkcji / Üretim Tarihi / Дата производства / Datum výroby / Gyártás dátuma / Datum výroby / Produktionsdato / Datum proizvodnje / Дата на производство / Data producției / Tootmise kuupäev / Izgatavošanas datums / Datum proizvodnje / Datum proizvodnje / Pagaminimo data / 生产日期 / 生産日期 / 제조일 / 製造日
	Caution / Attention / Vorsicht / Attenzione / Precaución / Cuidado / Opgelet / Försiktighetsåtgärd / Forsigtig / Varoitus / Προσοχή / Przestroga / Dikkat / Внимание / Výstraha / Figyelem! / Upozornenie / Advarsel / Pozor / Внимание / Atentie / Ettevaatust / Uzmanību! / Oprez / Oprez / Dėmesio / 注意 / 注意 / 주의 / 注意
	Manufacturer / Fabricant / Hersteller / Produttore / Fabricante / Fabricante / Fabrikant / Tillverkare / Producent / Valmistaja / Κατασκευστής / Producent / Üretici / Производител / Výrobce / Gyártó / Výrobca / Produsent / Proizvajalec / Производител / Producător / Tootja / Ražotājs / Proizvođač / Proizvođači / Gamintojas / 製造商 / 製造商 / 제조사 / 製造元
	Country of Manufacture (Made in the US) / Pays de fabrication (Fabriqué aux États-Unis) / Herstellungsland (Hergestellt in den USA) / Paese di produzione (fabbricato negli Stati Uniti) / País de fabricación (Hecho en EE. UU.) / País de fabricação (Feito nos Estados Unidos) / Land van vervaardiging (gemaakt in de Verenigde Staten) / Tillverkningsland (Tillverkad i USA) / Fremstillingsland (fremstillet i USA) / Valmistusmaa (valmistettu Yhdysvalloissa) / Χώρα κατασκευής (Κατασκευασμένο στις ΗΠΑ) / Kraj produkcji (Wyprodukowano w USA) / Üretildiği Ülke (ABD Məlidiir) / Страна производства (сделано в США) / Země výroby (vyrobeno v USA) / A gyártó országa (Made in the US) / Krajina výroby (vyroben v USA) / Produktionsland (produziert i USA) / Država proizvajalca (izdelano v ZDA) / Страна производел (Произведено в САЩ) / Țara de fabricație (Fabricat în SUA) / Valmistajariik (valmistatud USA-s) / Ražotājvalsts (Ražots ASV) / Zemlja proizvođača (proizvedeno u SAD-u) / Zemlja proizvodnje (proizvedeno u SAD) / Pagaminimo šalis (pagaminta JAV) / 生产国 (美国制造) / 生産國 (美國製造) / 제조국 (미국산) / 製造國 (米國製)
	Do not use if package is damaged / Ne pas utiliser si l'emballage est endommagé / Nicht verwenden, wenn die Verpackung beschädigt ist / Non utilizzare in caso di imballaggio danneggiato / No utilizar si el paquete está dañado / Não use se a embalagem estiver danificada / Niet gebruiken als de verpakking beschadigd is / Får inte användas om förpackningen är skadad / Må ikke bruges, hvis emballagen er beskadiget / Älä käytä, jos pakkaus on vahingoittunut / Μην χρησιμοποιείτε αν η συσκευασία είναι καταστραμμένη / Nie używać, jeśli opakowanie jest uszkodzone / Ambalaj hasarlıysa kullanmayın / Не использовать, если упаковка повреждена / Nepoužívejte, pokud je obal poškozen / Ne használja, ha a csomagolás sérült / Nepoužívejte, ak je obal poškodený / Ikke bruk hvis pakningen er skadet / Ne uporabljajte, če je ovoj poškodovan / Да не се използва, ако опаковката е повредена / A nu se utiliza dacă ambalajul este deteriorat / Mitte kasutada, kui pakend on viga saanud / Nelietote, ja iepakojums ir bojāts / Nemojte upotrebljavati ako je ambalaza oštećena / Ne koristite ako je pakovanje oštećeno / Nenaudokite, jei pakavotė pažeista / 如果包装破损, 请勿使用 / 如果包装損壞, 請勿使用 / 포장에 손상된 경우 사용하지 마십시오 / 梱包が破損している場合は使用しないこと
	Medical Device / Dispositif médical / Medizinprodukt / Dispositivo medico / Dispositivo médico / Dispositivo Médico / Medisch hulpmiddel / Medicinsk apparat / Medicinsk udstyr / Lääketieteellinen laite / Ιατρική συσκευή / Wyórób medyczny / Tibbi Cihaz / Медицинское изделие / Lékařské zařízení / Orvostechinikai eszköz / Zdravotnické pomůcky / Medicinsk utstyr / Medicinski pripomoček / Медицинско изделие / Dispozitiv medical / Meditsiiniiseade / Mediciniska ierice / Medicinski uređaj / Medicinski uređaj / Medicinos prietaisai / 医疗器械 / 醫療器械 / 의료 기기 / 医療機器
	Authorized Representative in the European Community/European Union / Représentant autorisé établi au sein de la Communauté européenne/l'Union européenne / Bevollmächtigte Vertretung in der Europäischen Gemeinschaft/Europäischen Union / Rappresentante autorizzato nella Comunità europea/Unione europea / Representante autorizado en la Comunidad Europea/Unión Europea / Representante Autorizado na Comunidade Europeia/União Europeia / Officiële vertegenwoordiger in de Europese Gemeenschap / Europese Unie / Auktoriserad representant inom Europeiska gemenskapen/Europeiska unionen / Autoriseret representant i Det Europeiske Fællesskab/Den Europæiske Union / Valtuutettu edustaja Euroopan yhteisössä/Euroopan unionissa / Ευκρινέως αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα/Ευρωπαϊκή Ένωση / Uroważniony przedstawiciel we Wspólnocie Europejskiej / Unii Europejskiej / Avrupa Topluluğu'nda/Avrupa Birliği'nde Yetkili Temsilci / Уполномоченный представитель в Европейском сообществе / Европейском союзе / Autorizovaný zástupce v Evropském společenství/Evropské unii / Meghatalmazott képviselő az Európai Közösségben/Európai Unióban / Oprávněný zástupce v Európskom spoločenstve/Európskej únii / Autoriseret representant i Det Europæiske felleskapet / EU / Pooblaščení predstavnik v Evropski skupnosti/Evropski uniji / Упълномощен представител в Европейската общност/Европейския съюз / Reprezentant autorizat în Comunitatea Europeană/Uniunea Europeană / Volitatud esindaja Euroopa Ühenduses / Euroopa Liidus / Pilnvarotais pārstāvis Eiropas Kopienā/Eiropas Savienībā / Ovlašteni predstavnik u Europskoj zajednici / Europskoj uniji / Ovlašteni predstavnik u Europskoj zajednici/Europskoj uniji / Įgaliotasis atstovas Europos Bendrijose / Europsos Sąjungoje / 欧洲共同体/欧洲联盟的授权代表 / 歐洲共同體/歐洲聯盟的授權代表 / 유럽 공동체/유럽 연합의 공인 대리인 / 欧洲共同体/欧洲連合の認定代理業者
	Unique Device Identifier / Identifiant unique du dispositif (UDI) / Eindeutige Gerätekennung / ID univoco del dispositivo / Identificador único del dispositivo / Identificador Único de Dispositivo / Unieke apparaat-id / Unik enhetsidentifierare / Unik etneds-ID / Yksilöllinen laitetunniste / Μοναδικό αναγνωριστικό συσκευής / Niepowtarzalny identyfikator wyrobu / Benzersiz Cihaz Kimliği / Уникальный идентификационный номер изделия / Jedinčný identifikátor zariadení / Egyedi eszközazonosító / Jedinčný identifikátor zariadenia / Unik (Unique Device Identifier) / Enolīni identifikatoris / Unikālais identifikators / Ovlašteni predstavnik u Europskoj zajednici / Europskoj uniji / Jedinstveni identifikator uređaja / Kordumatu identitiseerimistunnus / Ierices unikālais identifikators / Ovlašteni predstavnik u Europskoj zajednici / Europskoj uniji / Įgaliotasis atstovas Europos Bendrijose / Europsos Sąjungoje / Unikalus prietaiso identifikatorius / 唯一设备标识符 / 唯一設備標識符 / 기기 고유 식별자 / 機器固有識別子
	Distributor / Distributeur / Vertriebsniederlassung / Distributor / Distribuidor / Distributeur / Distributor / Jakelija / Διανομέας / Dystrybutor / Distribütör / Дистрибьютер / Distributor / Forgalmazó / Distribütör / Distributør / Distributer / Дистрибутор / Distributor / Edasimüüja / Izplatītājs / Distributer / Distributer / Platintojas / 经销商 / 經銷商 / 유통사 / 販売業者
	Importer / Importateur / Importniederlassung / Importatore / Importador / Importador / Importeur / Importør / Importör / Importør / Maahantuaja / Εισαγωγέας / Importer / İthalatçı / Импортёр / Importer / Importör / Dovoza / Importer / Uvoznik / Вноситец / Importator / Importija / Importētājs / Uvoznik / Importuotojas / 进口商 / 進口商 / 수입사 / 輸入業者
	Model Number / Numéro de modèle / Modellnummer / Codice modello / Número de modelo / Número do modelo / Modelnummer / Modellnummer / Modelnummer / Mallinúmero / Αρ. μοντέλου / Numer modelu / Model numarası / Номер модели / Císlu modelu / Modellszám / Císlu modelu / Modellnummer / Številka modela / Номер на модел / Număr model / Model number / Modelja numurs / Broj modela / Broj modela / Modelo numeris / 型号 / 型號 / 모델 번호 / モデル番号
Not made with natural rubber latex. / Ne contient pas de latex de caoutchouc naturel. / Ohne Naturkautschuklatex hergestellt. / Non fabbricato con lattice di gomma naturale. / No hecho con látex de caucho natural. / Não fabricado com látex de borracha natural. / Niet gemaakt met natuurlijk rubber latex. / EJ tilverkad med latex naturgummi. / Ikke fremstillet med naturgummilæksa. / Δεν κατασκευάζεται με τη χρήση φυσικού λάτεξ. / Nie jest wykonana z naturalnego lateksu gumowego. / Doğal kauçuk lateksten yapılmamıştır. / При производстве не использовался латекс натурального каучука. / Pfi výroby nebyl použit přírodní kaučukový latex. / Nem természetes gumból készült. / Nie je vyrobené z prírodného latexu. / Ikke laget av naturlig gummilæksa. / Ni izdelano iz naravnega gume iz lateksa. / Не съдържа естествен латекс. / Nu este fabricat din latex de cauciuc natural. / Pole valmistatud loodusliku kummilæksiga. / Nesatur dabiğā kaučuka lateksu. / Nije proizveden od prirodnog gumenog lateksa. / Ne sadrži prirodni gumeni lateks. / Pagaminta nenaudojant gamtinio kaučiuko lateksu. / 并非由天然乳胶制成. / 並非由天然膠乳製成. / 천연 고무 라텍스로 제작되지 않음. / 天然ゴムラテックス製ではありません.	






EC

REP

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