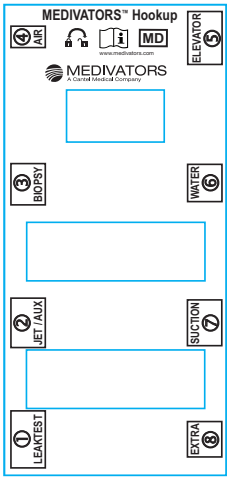
Hookup Connector Assembly Replacement Instructions

Using MEDIVATORS™ ADVANTAGE PLUS™ Reprocessors, ADVANTAGE PLUS™ Pass-Thru Reprocessors and ISA™ Reprocessors.

REF 2-8-611 / 2-8-611HAN / 2-8-611CAS

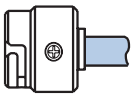
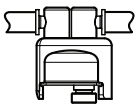
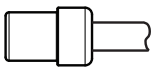
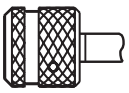
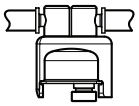
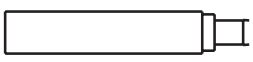
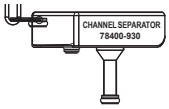
Hookup Diagram



Directions for Replacement of Connector Assemblies

1. Identify if the Hookup Connector Block is the new (*Figure 1 below*) or previous (*Figure 2 below*) design.
2. Identify current Connector Assembly on the Hookup Connector Block to be replaced.
3. Remove current Connector Assembly by pulling associated tubing **B** from the Hookup Connector Block Barb **A** (**NOTE:** If using the previous design, unscrew the Connector Coupling **F** of Connector Assembly from the Port Connector **C**, keeping the Port Connector firmly held in place and pull the tubing off the Port Connector stem **D**). Discard this Connector Assembly.
4. Retrieve the enclosed new Connector Assembly. **NOTE:** that it may not be identical to the Connector Assembly it is replacing. Discard Ferrule **E** and Connector Coupling **F** if using the new design. Confirm Connector Assembly labeling matches the Hookup Connector Block Label Port Name and the Port ID Number using the Connector Assembly Identification Chart. **NOTE:** Port ID Number may not be identified on some older Hookup Connector Block labels.
5. Push tubing **B** of the new Connector Assembly onto the Hookup Connector Block Barb **A**. **NOTE:** If experiencing difficulty in attaching the tubing to the Hookup Connector Block Barb **A**, dip the tip of the tubing into hot water for 10 seconds. (**NOTE:** If using the previous design, push tubing of new Connector Assembly onto the Port Connector Stem **C** and manually screw Connector Coupling **F** onto Port Connector **C** until tight. Do not over tighten. Ensure Port Connector **C** does not turn. If needed, use a wrench to prevent turning.)

Connector Assembly Identification Chart

Port ID	Port Name	Order No.	Connector
1	LEAK TEST	H28611-1	
2	JET/AUX	H28611-26	
3	BIOPSY	H28611-3	
4	AIR	H28611-4	
5	ELEVATOR	H28611-5	
6	WATER	H28611-26	
7	SUCTION	H28611-7	
8	EXTRA	N/A	N/A
S	N/A	78400-930	

If a Connector Assembly needs replacement, locate the Port Number/Name and use the corresponding order number found in the chart above. Connector Assemblies are specific to individual hookups.

Hookup Connector Block Types

Exploded view of Port Connector, Coupling Connector, Ferrule and Tubing:

Figure 1 - New Design

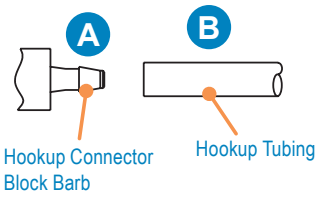
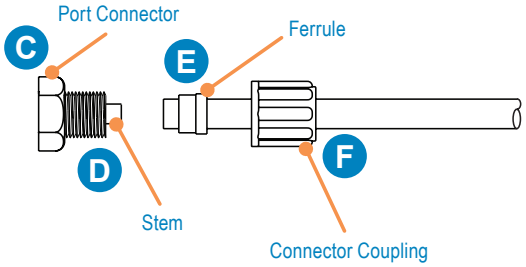


Figure 2 - Previous Design



NOTE: Ferrule must be present to prevent leaking.

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Warnings & Precautions

- This hookup is intended for connection only with the specific endoscope models identified in the appropriate Medivators online hookup guide. Use of this hookup with endoscopes other than those specified by the online hookup guide may result in inadequate HLD.
- Users operating Medivators AERs and hookups must be trained and competent in the understanding of endoscope channel systems.
- Prior to reprocessing, users must verify that the hookup used contains connections for all appropriate channels that require a separate reprocessing connection according to the hookup instructions.
- All connectors and adapters must remain firmly attached and unrestricted for the entire disinfection cycle to ensure adequate HLD. Users must inspect the endoscope and hookup combination to verify proper connection and flow.
- Modifications or repairs to hookups which do not correspond to the manufacturer's specifications may result in inadequate HLD and/or damage to endoscopes.
- Failure to properly clean and prepare endoscope for immersion prior to hookup connection may result in inadequate HLD and/or damage to the endoscope.
- Endoscopes must be inspected for damage and verified to be in proper working order prior to hookup connection. Connection of hookups to damaged endoscopes or endoscopes with obstructed/restricted channels could result in inadequate HLD.
- Manual leak testing must be carried out in accordance with manufacturer's recommendations prior to reprocessing.
- Install all necessary waterproof caps, plugs and cleaning adapters prior to immersion.
- Do NOT autoclave Medivators hookups.
- Medivators makes no claim on high-level disinfection efficacy when these reprocessing instructions are not followed, or when this hookup kit is applied to endoscopes other than those specified in the online interactive hookup guide.
- Avoid biological contamination. Always wear personal protective equipment when handling endoscopes.

If you have any questions regarding this hookup, in the United States, please contact Cantel Medivators Technical Support Representative at 1-800-444-4729. Outside the United States, please contact your Medivators representative.

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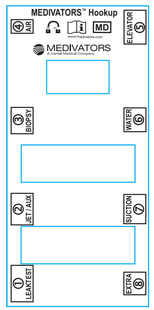
Hookup Connection Instructions for Use

Using MEDIVATORS™ ADVANTAGE PLUS™ Reprocessors, ADVANTAGE PLUS™ Pass-Thru Reprocessors and ISA™ Reprocessors.

REF 5-8-112, 5-8-112HAN, 5-8-112CAS

Locate the endoscope port and follow the instructions for attaching the corresponding Endoscope Connector. All connectors must be attached. Ensure the hookup block is appropriately connected to the base of the AER.

Hookup Diagram

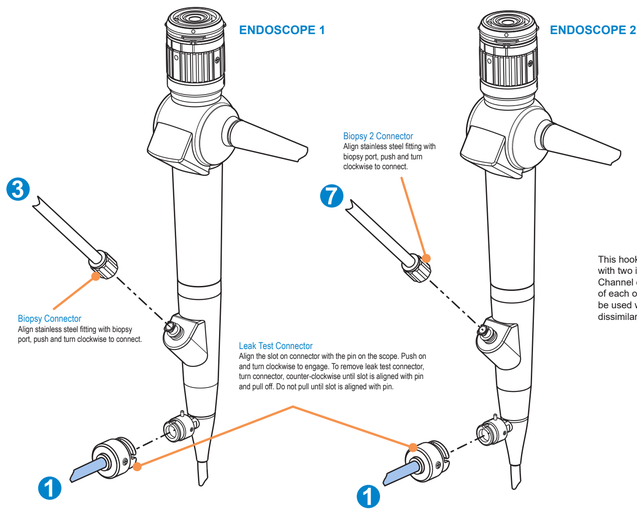


Each Hookup is comprised of multiple ports and connector assemblies. Each port is labeled with a Port ID number (circled). This same number also identifies the corresponding Connector Assembly. Each Connector Assembly is fitted with a specific endoscope connector.

Connector Assembly Identification Chart

Port ID	Port Name	Connector Assembly Description	Order No.
1	LEAK TEST	Leak Test Connector Assembly	H58112-1
2	JET/AUX	Air/Water Connector Assembly	N/A
3	BIOPSY	Biopsy Inlet Connector Assembly	H58112-3
4	AIR	Air Probe Connector Assembly	N/A
5	ELEVATOR	Auxiliary Water Connector Assembly	N/A
6	WATER	Air/Water Connector Assembly	N/A
7	SUCTION	Biopsy 2 Inlet Connector Assembly	H58112-7
8	EXTRA	N/A	N/A
S	N/A	N/A	N/A

Connector Assemblies are specific to individual hookups.



This hookup is designed to be used with two identical endoscope models. Channel connections are duplicates of each other. This hookup cannot be used with only one endoscope or dissimilar models.

Representative endoscope for illustrative purposes only. For exact port locations, refer to endoscope manufacturer's instruction guide.

Designated Hookup

For the Following PENTAX® Endoscopes*					
CHF-10	CHF-B260	CHF-CB20	CHF-CB30L	CHF-CB30S	CHF-P10
CYF	CYF-2	CYF-200	CYF-240	CYF-3	CYF-4
CYF-5	CYF-5R	CYF-V	CYF-V2	CYF-V2R	CYF-VH
CYF-VHR	HYF-P	HYF-V	HYF-XP	SIF-SW	URF-P
URF-P2	URF-P3	URF-P5	URF-V	URF-P7	URF-P7R
URF-P2	URF-P3	URF-P5	URF-V	URF-P7	URF-P7R
URF-V3	URF-V3R				

*This list of corresponding endoscope models is subject to change without notice. For a full list, please go to: www.medivators.com/hookuplookup

*Not all endoscopes may be available in every region. Contact your local representative for device availability.

Intended Purpose

Hookups are intended to provide the interface between an Automatic Endoscope Reprocessor (AER) and endoscopes, which allow perfusion of liquids dispensed by the AER to contact and high-level disinfect the channels of flexible endoscopes.

Clinical Benefit

This ability of the device to flush endoscope channels with high-level disinfection during the reprocessing cycle of fully immersible endoscopes helps reduce post-endoscopic infections, thereby ensuing patient safety.

Warnings & Precautions

- Ensure proper alignment of all connectors with the endoscope mating parts prior to attachment.
- This hookup is intended for connection only with the specific endoscope models identified in the appropriate Medivators online hookup guide. Use of this hookup with endoscopes other than those specified by the hookup application guide may result in inadequate HLD.
- Users operating Medivators AERs and hookups must be trained and competent in the understanding of endoscope channel systems.
- Prior to reprocessing, users must verify that the hookup used contains connections for all appropriate channels that require a separate reprocessing connection according to the hookup instructions.
- All connectors and adapters must remain firmly attached and unrestricted for the entire disinfection cycle to ensure adequate HLD. Users must inspect the endoscope and hookup combination to verify proper connection and flow.
- Modifications or repairs to hookups which do not correspond to the manufacturer's specifications may result in inadequate HLD and/or damage to endoscopes.
- Failure to properly clean and prepare endoscope for immersion prior to hookup connection may result in inadequate HLD and/or damage to the endoscope.
- Endoscopes must be inspected for damage and verified to be in proper working order prior to hookup connection. Connection of hookups to damaged endoscopes or endoscopes with obstructed/restricted channels could result in inadequate HLD.
- Manual leak testing must be carried out in accordance with manufacturer's recommendations prior to reprocessing.
- Install all necessary waterproof caps, plugs and cleaning adapters prior to immersion.
- Do not autoclave Medivators hookups.
- Medivators makes no claim on high-level disinfection efficacy when these reprocessing instructions are not followed, or when this hookup kit is applied to endoscopes other than those specified in the online interactive hookup guide.
- Avoid biological contamination. Always wear personal protective equipment when handling endoscopes.
- An Advantage Hookup Cassette combines an endoscope tray with the hookup connector block and are designated with a CAS suffix (applicable to metal cassette only). Specific endoscope connections for this hookup are identical to non-cassette versions.

Adverse Event Reporting

User facilities shall report adverse events to Medivators, a Cantel Medical company, as well as the competent authority of the EU member state in which the user is established, if applicable.

If you have any questions regarding this hookup, in the United States, please contact Cantel Medivators Technical Support Representative at 1-800-444-4729. Outside the United States, please contact your Medivators representative.

For additional symbols reference information, definition and translation, please reference the Cantel Symbols Glossary on the Medivators website, www.medivators.com.

English

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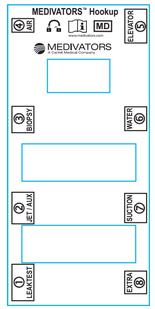
Instructions d'utilisation des connexions de raccordement

Utilisation des postes de retraitement MEDIVATORS™ ADVANTAGE PLUS™, des postes de retraitement ADVANTAGE PLUS™ Pass-Thru et des postes de retraitement ISA™.

REF 5-8-112, 5-8-112HAN, 5-8-112CAS

Localisez le port de l'endoscope et suivez les instructions pour fixer le connecteur d'endoscope correspondant. Tous les connecteurs doivent être fixés. Assurez-vous que le bloc de raccordement est connecté de manière appropriée à la base de l'AER.

Schéma de raccordement

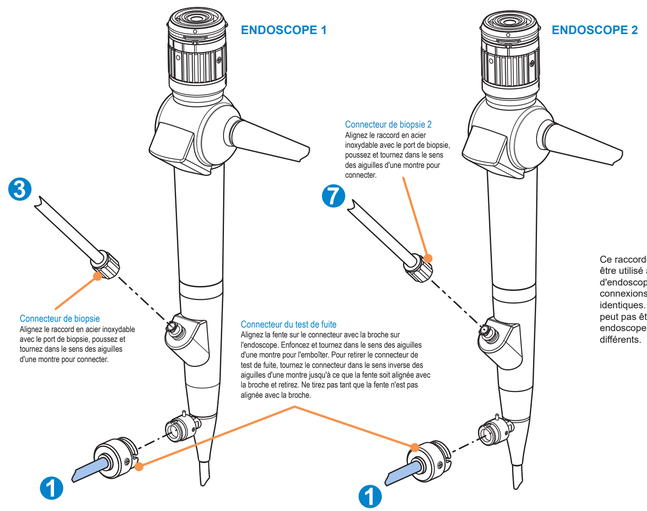


Chaque raccordement est composé de plusieurs ports et de plusieurs assemblages de connecteurs. Chaque port est étiqueté avec un numéro ID de port (entouré). Ce même numéro identifie également l'assemblage de connecteur correspondant. Chaque assemblage de connecteur est équipé d'un connecteur d'endoscope spécifique.

Tableau d'identification des assemblages de connecteurs

ID du port	Nom du port	Description de l'assemblage de connecteur	N° de commande
1	TEST DE FUITE	Assemblage de connecteur de test de fuite	H58112-1
2	JET/AUX	Assemblage de connecteur d'air/d'eau	S.O.
3	BIOPSIE	Assemblage de connecteur d'entrée de biopsie	H58112-3
4	AIR	Assemblage de connecteur de sonde d'air	S.O.
5	ÉLÉVATEUR	Assemblage du connecteur d'eau auxiliaire	S.O.
6	EAU	Assemblage de connecteur d'air/d'eau	S.O.
7	ASPIRATION	Assemblage de connecteur d'entrée de biopsie 2	H58112-7
8	SUPPLÉMENTAIRE	S.O.	S.O.
S	S.O.	S.O.	S.O.

Les assemblages de connecteurs sont spécifiques à des raccordements individuels.



Ce raccordement est conçu pour être utilisé avec deux modèles d'endoscope identiques. Les connexions des canaux sont identiques. Ce raccordement ne peut pas être utilisé avec un seul endoscope ou avec des modèles différents.

Endoscope représentatif à des fins d'illustration uniquement. Pour les emplacements exacts des ports, reportez-vous au guide d'instructions du fabricant de l'endoscope.

Raccordement désigné

Pour les endoscopes PENTAX® suivants*					
CHF-10	CHF-B260	CHF-CB20	CHF-CB30L	CHF-CB30S	CHF-P10
CYF	CYF-2	CYF-200	CYF-240	CYF-3	CYF-4
CYF-5	CYF-5R	CYF-V	CYF-V2	CYF-V2R	CYF-VH
CYF-VHR	HYF-P	HYF-V	HYF-XP	SIF-SW	URF-P
URF-P2	URF-P3	URF-P5	URF-V	URF-P7	URF-P7R
URF-P2	URF-P3	URF-P5	URF-V	URF-P7	URF-P7R
URF-V3	URF-V3R				

*Cette liste de modèles d'endoscopes correspondants est soumise à des modifications sans préavis. Pour une liste exhaustive, veuillez accéder au site : www.medivators.com/hookuplookup

*Certains endoscopes sont susceptibles de ne pas être disponibles dans chaque région. Contactez votre représentant local pour connaître la disponibilité des dispositifs.

Utilisation prévue

Les raccordements sont destinés à établir l'interface entre un poste de retraitement automatique des endoscopes (AER) et les endoscopes, ce qui permet à la perfusion de liquides distribués par l'AER d'entrer en contact avec les canaux des endoscopes flexibles et d'assurer leur désinfection de haut niveau.

Bénéfice clinique

Cette capacité du dispositif à rincer les canaux de l'endoscope avec une désinfection de haut niveau durant le cycle de retraitement des endoscopes entièrement immersibles permet de réduire les infections post-endoscopiques, garantissant par là même la sécurité du patient.

Avertissements et précautions

- Assurez l'alignement adéquat de tous les connecteurs avec les pièces de couplage de l'endoscope avant la fixation.
- Ce raccordement est destiné à être connecté uniquement avec les modèles d'endoscopes spécifiques identifiés dans le guide en ligne approprié des raccordements de Medivators. L'utilisation de ce raccordement avec des endoscopes autres que ceux spécifiés par le guide d'application des raccordements peut entraîner une désinfection de haut niveau (DHN) inadéquate.
- Les utilisateurs employant les AER et les raccordements de Medivators doivent être formés et familiarisés avec les systèmes de canaux des endoscopes.
- Avant le retraitement, les utilisateurs doivent vérifier que le raccordement utilisé contient les connexions pour tous les canaux appropriés qui nécessitent une connexion de retraitement distincte selon les instructions du raccordement.
- Tous les connecteurs et adaptateurs doivent rester solidement fixés et libres durant l'intégralité du cycle de désinfection pour garantir une DHN adéquate. Les utilisateurs doivent inspecter la combinaison endoscope-raccordement pour vérifier que la connexion et le débit sont corrects.
- Les modifications ou les réparations des raccordements qui ne correspondent pas aux spécifications du fabricant peuvent entraîner une DHN inadéquate et/ou endommager les endoscopes.
- L'incapacité à nettoyer et à préparer correctement l'endoscope pour l'immersion avant la connexion du raccordement peut entraîner une DHN inadéquate et/ou endommager l'endoscope.
- Les endoscopes doivent être inspectés à la recherche de dommages et ils doivent faire l'objet d'une vérification pour s'assurer qu'ils sont en bon état de marche avant la connexion du raccordement. La connexion de raccordements à des endoscopes endommagés ou à des endoscopes présentant des canaux obstrués/limités pourrait entraîner une DHN inadéquate.
- Un test de fuite manuel doit être effectué conformément aux recommandations du fabricant avant le retraitement.
- Installez tous les capuchons étanches, tous les bouchons et tous les adaptateurs de nettoyage nécessaires avant l'immersion.
- N'autoclavez pas les raccordements de Medivators.
- Medivators ne fait aucune déclaration quant à l'efficacité de la désinfection de haut niveau lorsque ces instructions de retraitement ne sont pas suivies ou lorsque ce kit de raccordement est appliqué à des endoscopes autres que ceux spécifiés dans le guide en ligne interactif des raccordements.
- Évitez toute contamination biologique. Portez systématiquement un équipement de protection individuelle lorsque vous manipulez des endoscopes.
- Une cassette de raccordement Advantage combine un plateau d'endoscope avec le bloc de connecteur de raccordement et est désignée avec un suffixe CAS (s'applique uniquement à une cassette en métal). Les connexions d'endoscope spécifiques pour ce raccordement sont identiques à celles des versions sans cassette.

Déclaration des événements indésirables

Les établissements des utilisateurs doivent déclarer les événements indésirables à Medivators, une société Cantel Medical, ainsi qu'à l'autorité compétente de l'État membre de l'UE dans lequel l'utilisateur réside, le cas échéant.

Pour toute question concernant ce raccordement, aux États-Unis, veuillez contacter le représentant du support technique de Cantel Medivators au 1-800-444-4729. En dehors des États-Unis, veuillez contacter votre représentant de Medivators.

Pour des informations de référence, des définitions et des traductions supplémentaires sur les symboles, veuillez consulter le glossaire des symboles de Cantel sur le site Web de Medivators, www.medivators.com.

French / Français

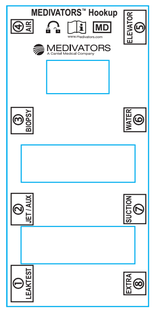
Instrucciones de uso del bloque de conexión

Uso de los reprocesadores MEDIVATORS™ ADVANTAGE PLUS™, reprocesadores ADVANTAGE PLUS™ Pass-Thru y reprocesadores ISA™.

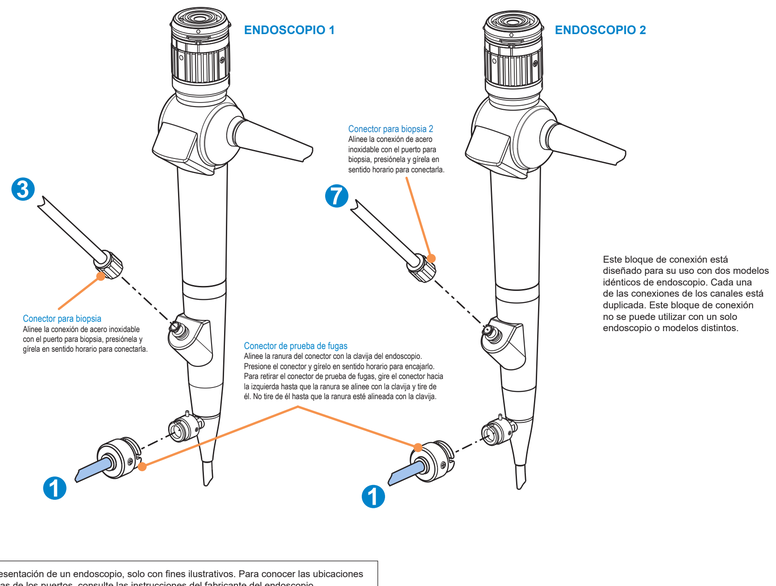
REF 5-8-112, 5-8-112HAN, 5-8-112CAS

Localice el puerto del endoscopio y siga las instrucciones para conectar el conector del endoscopio correspondiente. Se deben conectar todos los conectores. Compruebe que el bloque de conexión esté correctamente conectado a la base del AER.

Diagrama del bloque de conexión



Cada bloque de conexión se compone de varios puertos y conjuntos de conectores. Cada puerto está etiquetado con un número de ID de puerto (dentro de un círculo). Este mismo número identifica también el correspondiente conjunto de conector. Cada conjunto de conector lleva un conector de endoscopio específico.



Este bloque de conexión está diseñado para su uso con dos modelos idénticos de endoscopio. Cada una de las conexiones de los canales está duplicada. Este bloque de conexión no se puede utilizar con un solo endoscopio o modelos distintos.

Representación de un endoscopio, solo con fines ilustrativos. Para conocer las ubicaciones exactas de los puertos, consulte las instrucciones del fabricante del endoscopio.

Tabla de identificación de los conjuntos de conectores

ID del puerto	Nombre del puerto	Descripción del conjunto de conector	N.º de referencia para pedidos
1	PRUEBA DE FUGAS	Conjunto de conector de prueba de fugas	H58112-1
2	JET/AUX	Conjunto de conector de aire/agua	N/A
3	BIOPSIA	Conjunto de conector de entrada para biopsia	H58112-3
4	AIRE	Conjunto de conector de sonda de aire	N/A
5	ELEVADOR	Conjunto de conector de agua auxiliar	N/A
6	AGUA	Conjunto de conector de aire/agua	N/A
7	ASPIRACIÓN	Conjunto de conector de entrada para biopsia 2	H58112-7
8	EXTRA	N/A	N/A
S	N/A	N/A	N/A

Los conjuntos de conectores son específicos para cada uno de los bloques de conexión.

Bloque de conexión designado

Para los endoscopios PENTAX® siguientes*					
CHF-10	CHF-B260	CHF-CB20	CHF-CB30L	CHF-CB30S	CHF-P10
CYF	CYF-2	CYF-200	CYF-240	CYF-3	CYF-4
CYF-5	CYF-5R	CYF-V	CYF-V2	CYF-V2R	CYF-VH
CYF-VHR	HYF-P	HYF-V	HYF-XP	SIF-SW	URF-P
URF-P2	URF-P3	URF-P5	URF-V	URF-P7	URF-P7R
URF-P2	URF-P3	URF-P5	URF-V	URF-P7	URF-P7R
URF-V3	URF-V3R				

*Esta lista de correspondencias de los modelos de endoscopios está sujeta a cambios sin previo aviso. Para obtener una lista completa, visite: www.medivators.com/hookuplookup

*Es posible que no todos los endoscopios estén disponibles en todas las regiones. Para conocer la disponibilidad de los dispositivos, póngase en contacto con el representante local.

Uso previsto

Los bloques de conexión están concebidos como una interfaz entre un reprocesador de endoscopio automático (AER) y los endoscopios, para permitir que los líquidos perfundidos, dispensados por el AER, entren en contacto con los canales de los endoscopios flexibles y brinden una desinfección de alto nivel de los mismos.

Beneficio clínico

Esta capacidad del dispositivo de lavar los canales de los endoscopios con una desinfección de alto nivel durante el ciclo de reprocesamiento de endoscopios de inmersión completa contribuye a reducir las infecciones posendoscópicas, brindando así seguridad al paciente.

Advertencias y precauciones

- Compruebe la correcta alineación de todos los conectores con las piezas correspondientes del endoscopio antes de la conexión.
- Este bloque de conexión está concebido para conectarlo únicamente con los modelos específicos de endoscopio que se identifican en la correspondiente guía en línea de bloques de conexión de Medivators. El uso de este bloque de conexión con endoscopios distintos de los especificados en la guía de aplicaciones de los bloques de conexión puede tener como resultado una incorrecta desinfección de alto nivel.
- Los usuarios que utilicen los AER y los bloques de conexión de Medivators deben haber recibido la formación correspondiente y ser competentes a la hora de comprender el funcionamiento de los sistemas de canales endoscópicos.
- Antes del reprocesamiento, los usuarios deben verificar que el bloque de conexión empleado contenga todas las conexiones para los canales pertinentes que requieran una conexión independiente de reprocesamiento según las instrucciones del bloque de conexión.
- Todos los conectores y adaptadores deben permanecer bien conectados y sin restricciones durante todo el ciclo de desinfección para garantizar una correcta desinfección de alto nivel. Los usuarios deben inspeccionar la combinación de endoscopio y bloque de conexión para verificar que la conexión y el flujo sean los adecuados.
- Si realiza modificaciones o reparaciones de los bloques de conexión que no se corresponden con las especificaciones del fabricante, podría causar una incorrecta desinfección de alto nivel o dañar los endoscopios.
- Si no limpia y prepara correctamente el endoscopio para su inmersión antes de la conexión del bloque de conexión, podría causar una incorrecta desinfección de alto nivel o dañar el endoscopio.
- Antes de conectarlos al bloque de conexión, los endoscopios se deben inspeccionar para comprobar que no están dañados y para verificar que funcionan correctamente. Si conecta bloques de conexión a endoscopios dañados o endoscopios cuyos canales estén obstruidos/restringidos, podría causar una incorrecta desinfección de alto nivel.
- Las pruebas manuales de fugas se deben llevar a cabo siguiendo las recomendaciones del fabricante antes del reprocesamiento.
- Antes de la inmersión, coloque todas las tapas, tapones y adaptadores de limpieza estancos que sean necesarios.
- No esterilice los bloques de conexión de Medivators en autoclave.
- Medivators no podrá garantizar la eficacia de la desinfección de alto nivel cuando no se sigan estas instrucciones de reprocesamiento, ni cuando este bloque de conexión se aplique a endoscopios distintos de los especificados en la guía en línea interactiva de bloques de conexión.
- Evite la contaminación biológica. Use siempre un equipo de protección individual cuando manipule los endoscopios.
- Los cassettes Advantage para bloque de conexión combinan la bandeja del endoscopio con el bloque de conexión y están designados con un sufijo CAS (solamente en el caso de los cassettes metálicos). Las conexiones para endoscopios específicos de este bloque de conexión son idénticas a las de las versiones sin cassette.

Notificación de acontecimientos adversos

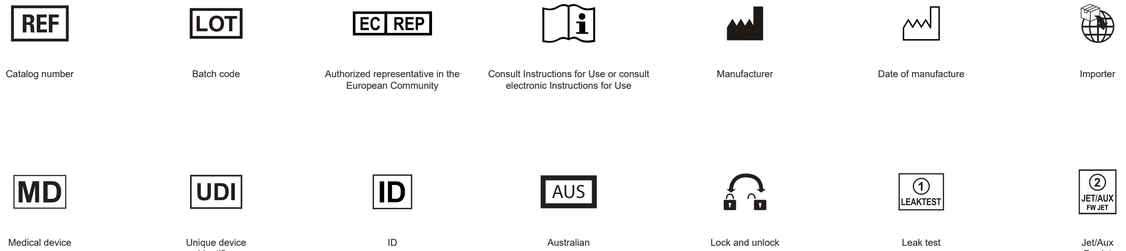
Los centros del usuario notificarán los acontecimientos adversos a Medivators, una empresa de Cantel Medical, así como a la autoridad competente del estado miembro de la UE en el que se encuentre establecido el usuario, si procede.

Si tiene alguna pregunta relativa a este bloque de conexión, en Estados Unidos, póngase en contacto con el representante de asistencia técnica de Cantel Medivators en el 1-800-444-4729. Fuera de Estados Unidos, póngase en contacto con el representante de Medivators.

Para obtener más información de referencia, definiciones y traducciones de los símbolos, consulte el glosario de símbolos de Cantel en el sitio web de Medivators, www.medivators.com.

Spanish / Español

Symbols



See AER symbols glossary or user manual for more information.

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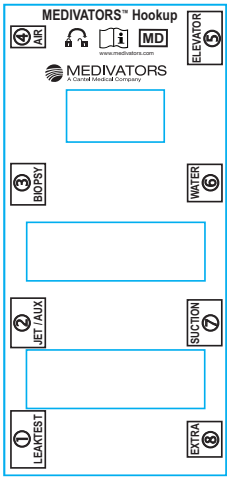
Hookup Connector Assembly Replacement Instructions

Using MEDIVATORS™ ADVANTAGE PLUS™ Reprocessors, ADVANTAGE PLUS™ Pass-Thru Reprocessors and ISA™ Reprocessors.

REF 2-8-332 / 2-8-332HAN / 2-8-332CAS

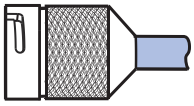
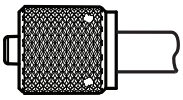
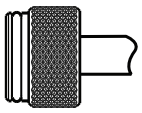
Hookup Diagram



Directions for Replacement of Connector Assemblies

1. Identify if the Hookup Connector Block is the new (*Figure 1 below*) or previous (*Figure 2 below*) design.
2. Identify current Connector Assembly on the Hookup Connector Block to be replaced.
3. Remove current Connector Assembly by pulling associated tubing **B** from the Hookup Connector Block Barb **A** (**NOTE:** If using the previous design, unscrew the Connector Coupling **F** of Connector Assembly from the Port Connector **C**, keeping the Port Connector firmly held in place and pull the tubing off the Port Connector stem **D**). Discard this Connector Assembly.
4. Retrieve the enclosed new Connector Assembly. **NOTE:** that it may not be identical to the Connector Assembly it is replacing. Discard Ferrule **E** and Connector Coupling **F** if using the new design. Confirm Connector Assembly labeling matches the Hookup Connector Block Label Port Name and the Port ID Number using the Connector Assembly Identification Chart. **NOTE:** Port ID Number may not be identified on some older Hookup Connector Block labels.
5. Push tubing **B** of the new Connector Assembly onto the Hookup Connector Block Barb **A**. **NOTE:** If experiencing difficulty in attaching the tubing to the Hookup Connector Block Barb **A**, dip the tip of the tubing into hot water for 10 seconds. (**NOTE:** If using the previous design, push tubing of new Connector Assembly onto the Port Connector Stem **C** and manually screw Connector Coupling **F** onto Port Connector **C** until tight. Do not over tighten. Ensure Port Connector **C** does not turn. If needed, use a wrench to prevent turning.)

Connector Assembly Identification Chart

Port ID	Port Name	Order No.	Connector
1	LEAK TEST	H28332-1	
2	JET/AUX	N/A	N/A
3	BIOPSY	H28332-3	
4	AIR	N/A	N/A
5	ELEVATOR	N/A	N/A
6	WATER	H28332-6	
7	SUCTION	H28332-7	
8	EXTRA	N/A	N/A
S	N/A	N/A	N/A

If a Connector Assembly needs replacement, locate the Port Number/Name and use the corresponding order number found in the chart above. Connector Assemblies are specific to individual hookups.

Hookup Connector Block Types

Exploded view of Port Connector, Coupling Connector, Ferrule and Tubing:

Figure 1 - New Design

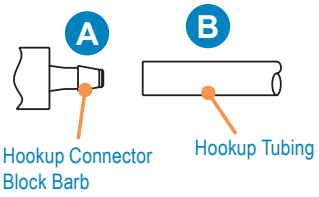
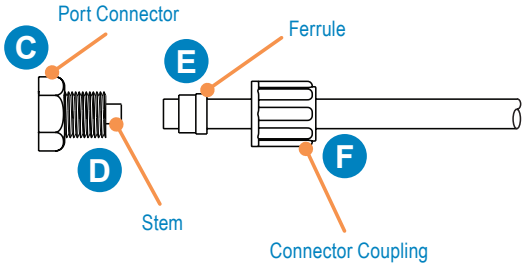


Figure 2 - Previous Design



NOTE: Ferrule must be present to prevent leaking.

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Warnings & Precautions

- This hookup is intended for connection only with the specific endoscope models identified in the appropriate Medivators online hookup guide. Use of this hookup with endoscopes other than those specified by the online hookup guide may result in inadequate HLD.
- Users operating Medivators AERs and hookups must be trained and competent in the understanding of endoscope channel systems.
- Prior to reprocessing, users must verify that the hookup used contains connections for all appropriate channels that require a separate reprocessing connection according to the hookup instructions.
- All connectors and adapters must remain firmly attached and unrestricted for the entire disinfection cycle to ensure adequate HLD. Users must inspect the endoscope and hookup combination to verify proper connection and flow.
- Modifications or repairs to hookups which do not correspond to the manufacturer's specifications may result in inadequate HLD and/or damage to endoscopes.
- Failure to properly clean and prepare endoscope for immersion prior to hookup connection may result in inadequate HLD and/or damage to the endoscope.
- Endoscopes must be inspected for damage and verified to be in proper working order prior to hookup connection. Connection of hookups to damaged endoscopes or endoscopes with obstructed/restricted channels could result in inadequate HLD.
- Manual leak testing must be carried out in accordance with manufacturer's recommendations prior to reprocessing.
- Install all necessary waterproof caps, plugs and cleaning adapters prior to immersion.
- Do NOT autoclave Medivators hookups.
- Medivators makes no claim on high-level disinfection efficacy when these reprocessing instructions are not followed, or when this hookup kit is applied to endoscopes other than those specified in the online interactive hookup guide.
- Avoid biological contamination. Always wear personal protective equipment when handling endoscopes.

If you have any questions regarding this hookup, in the United States, please contact Cantel Medivators Technical Support Representative at 1-800-444-4729. Outside the United States, please contact your Medivators representative.

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THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

CANTEL MEDICAL (ITALY) SRL

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

has implemented and maintains a

Quality Management System

for the following scope:

Design, development, manufacturing of disinfectants, sterilizers and detergents for medical devices. Design, development, production, sales and technical service of device for washing, disinfection and sterilization of medical devices. Design, development, production management of conservation and transport systems for endoscopes

Further clarifications regarding the applicability of UNI CEI EN ISO 13485:2016 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

UNI CEI EN ISO 13485:2016

Issued on: **2021 - 01 - 21**
Expires on: ***2024 - 07 - 05***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 126041

Alex Stoichitoiu
President of IQNET

Ing. Mario Romersi
President of CISQ

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* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

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IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. 1250.2019

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CANTEL MEDICAL (ITALY) SRL

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, sviluppo, produzione di disinfettanti, sterilizzatrici e detergenti per dispositivi medici. Progettazione, sviluppo, produzione, commercializzazione e assistenza tecnica di dispositivi per il lavaggio, la disinfezione e la sterilizzazione di dispositivi medici. Progettazione, sviluppo, gestione della produzione di sistemi di conservazione e trasporto di endoscopi
Design, development, manufacturing of disinfectants, sterilizers and detergents for medical devices. Design, development, production, sales and technical service of device for washing, disinfection and sterilization of medical devices. Design, development, production management of conservation and transport systems for endoscopes

Ulteriori informazioni riguardanti l'applicabilità dei requisiti UNI CEI EN ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of UNI CEI EN ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1997-07-25	2021-01-21	2024-07-05

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

La data di prima certificazione è riferita al rilascio da parte di altro Organismo
First certification date is related to issue date of another Certification Body

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

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U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 14038-9-2020

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(Three Pages)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from September 18, 2020 to September 17, 2022.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
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Silver Spring, MD 20993
www.fda.gov

Certificate No. 14038-9-2020
Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

MEDIVATORS
14605 28TH AVE NORTH
Minneapolis, MN USA 55447

Name of Manufacturer

Medivators Inc
14605 28th Ave N
MINNEAPOLIS, MN USA 55447

Medivators Inc
3150 Pollok Drive
Conroe, TX USA 77303

----END OF MANUFACTURER/DISTRIBUTOR LIST----

U.S. FOOD & DRUG ADMINISTRATION
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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 3

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MINNEAPOLIS, MN USA 55447

Medivators Inc
3150 Pollok Drive
Conroe, TX USA 77303

Name of Product(s)

Renatron PA Dialyzer Reprocessing System
Renatron PA 100 Dialyzer Reprocessing System-- RS-8315
Renatron II Dialyzer Reprocessing System
Renatron II 100 Dialyzer Reprocessing System-- RS-8335
Renalog RM-- 78398-192, 78398-204
Renalin Cold Sterilant-- 78397-521
Renalin PA Cold Sterilant-- 78397-638, 78397-639, 78397-452
Renalin 100 Cold Sterilant-- 78398-060, 78397-844, 78397-845, 78397-846, 78397-970
Renalin 100 Cold Sterilant with test kit-- 78397-845, 78397-846, 78397-970
Renalin Indicator Test Strips --78199-000
Renalin Residual Test Strips-- 78198-000
Perassay 500 Peracetic Acid Test Strips-- 78378-000
Actril Cold Sterilant-- 78337-000, 78399-667
Actril Cold Sterilant with test kit-- 78270-000
Actril Residual Test Strips-- 78258-000
Actril Indicator Test Strips-- 78259-000
Hemocor HPH Hemoconcentrator; HPH Mini, HPH Junior
Hemocor HPH Hemoconcentrator; HPH 400, HPH 400TS
Hemocor HPH Hemoconcentrator; HPH 700, HPH 700TS
Hemocor HPH Hemoconcentrator; HPH 1000, HPH 1000TS
Hemocor HPH Hemoconcentrator; HPH 1400, HPH 1400TS
Renaflo II Hemofilter; HF Minifilter Plus
Renaflo II Hemofilter; HF Junior
Renaflo II Hemofilter; HF400
Renaflo II Hemofilter; HF700
Renaflo II Hemofilter; HF1200
Renaflo II Hemofilter; HF2000
Primus Hollow Fiber Dialyzer; Primus 1350
Fiberflo Hollow Fiber Cartridge Water Filter--FF50, FF100, FF200
Bicarbonate Concentrate Liquid; BC-1-L Renasol, MB-330-L Centrisol
Bicarbonate Concentrate Powder; Renasol BC-1, BC-1-15, BC-1-25
Bicarbonate Concentrate Powder; Centrisol MB-330, MB-330-15, MB-330-25
Acetate Concentrate Nephrosol; Acetate Concentrate
Renasol Acid Concentrate - SB-1003, SB-1014, SB-1019, SB-1020, SB-1030, SB-1057, SB-1063, SB-1078, SB-1086
Centrisol Acid Concentrate - SB-111, SB-119, SB-123, SB-127, SB-129, SB-140, SB-142, SB-143, SB-144, SB-145
Medivators Advantage Plus Endoscope Reprocessing System
Medivators Advantage Automated Endoscope Reprocessor
MDS Modular Disinfection System
ADVANTAGE PLUS Pass-Thru Automatic Endoscope Reprocessor -- ADVPT-3005, ADVPT-3006
DSD Series Automatic Endoscope Reprocessor-- DSD-201(LT)(Model No.: DSD-2007, DSD-2011), SSD-102(LT)

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Certificate No. 14038-9-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 3

DSD Series Automatic Endoscope Reprocessor-- DSD Edge
CER Series Endoscope Reprocessor-- CER-1, CER-2, CER-1 Optima, CER-2 Optima
Veriscan Automated Endoscope Leak Detection System-- VER-LT
Rapicide PA High-Level Disinfectant-- ML02-0117, ML02-0116, ML02-0115
Rapicide OPA-28 High-Level Disinfectant-- ML02-0127, ML02-0132, ML02-0138
Rapicide PA RTU High-Level Disinfectant & Sterilant- ML02-0125
Rapicide High-Level Disinfectant and Sterilant-- ML02-0059, ML02-0108
Rapicide PA Disinfectant & Sterilant Test Strips - ML02-0118
Rapicide PA RTU High-Level Disinfectant & Sterilant Test Strips - ML02-0129
Rapicide OPA-28 Test Strips-- ML02-0137, ML02-0136
Rapicide Test Strips-- ML02-0120
MediClean EZ-- ML02-0131
Intercept Detergent-- ML02-0106, ML02-0134
Intercept Plus - ML02-0145
Intercept Wipes-- ML02-0107
Intercept Foam - ML02-0139
Scope Buddy Endoscope Flushing Aid-- EFA-US-G, EFA-IN-G (Model No. ECA-100G)
Scope Buddy Tubing Accessory Kit- 78399-669
Minncare Cold Sterilant -78398-229, 78397-983, 78397-825
Minncare Residual Test Strips -78338-000
Minncare Peracetic Acid Test Strips- 78339-000
EndoStratus Irrigation Pump EGA-500, EGA-500E, EGA-500P
EndoGator Irrigation Pump EGP-100, EGP-100E, EGP-100P
EndoStratus CO2 Insufflator EGA-501, EGA-501E, EGA-501P
EndoStratus Irrigation Pump and CO2 Insufflator System -- EGA-SYST
EndoSmartCap Irrigation Tubing and Accessories 100145, 100145U, 100145CO2, 100145CO2U
ENDO SMARTCAP Co2 Tubing 100145CO2EX, 100150CO2EX,100165CO2EX
EndoSmartCap Irrigation Tubing and Accessories 100150CO2P
EndoSmartCap Irrigation Tubing and Accessories 100150, 100150U, 100150CO2, 100150CO2U
EndoSmartCap Irrigation Tubing and Accessories 100160, 100160U, 100160P,100160S
EndoSmartCap Irrigation Tubing and Accessories 100165, 100165U 100165CO2, 100165CO2U
EndoSmartCap Irrigation Tubing and Accessories 100140, 100141, 100551, 100551P
EndoSmartCap Irrigation Tubing and Accessories 100162
EndoSmartCap Adapter 100555
ENDOGATOR Cartridge 100110
EndoGator Hybrid Irrigation Tubing 100605, 100605U, 100605S,100606, 100606U, 100606S
EndoGator Hybrid Irrigation Tubing 100608, 100608U,100608S, 100609, 100609U,100609S
EndoGator Hybrid Irrigation Tubing 100610, 100610U, 100610S
EndoGator Hybrid Irrigation Tubing 100630, 1001630U, 100631, 100631U
EndoGator Irrigation Tubing and Accessories Kits 100130P,100130, 100130U,100130F,100130FU
EndoGator Irrigation Tubing and Accessories Kits 100125, 100125F, 100126
EndoGator Irrigation Tubing and Accessories Kits 200230P
EndoGator Irrigation Tubing and Accessories Kits 200230, 200230U, 200230F, 200230FU
EndoGator Irrigation Tubing and Accessories Kits 100135, 100136, 100105
EndoGator Irrigation Tubing and Accessories Kits 100131, 100115, 100116, 100116P
EndoGator Irrigation Tubing and Accessories Kits 100241, 100242, 100242P, 100115, 100116
EndoGator Irrigation Tubing and Accessories Kits 100600, 100601, 100602
EndoGator Irrigation Tubing and Accessories Kits 100603, 100611, 100612, 100613, 100614
EndoGator Irrigation Tubing and Accessories Kits 100615, 100616, 100618
EndoGator Irrigation Tubing and Accessories Kits 100620, 100621, 100622, 100623
EndoGator Irrigation Tubing and Accessories Kits 100625, 100626, 100627, 100628, 100629
EndoGator Irrigation Tubing and Accessories Kits 100630, 100630S, 100631,100631S
Defendo Disposable Biopsy, Air/Water and Suction Valves 100301, 100302, 100303, 100305
Defendo Disposable Biopsy, Air/Water and Suction Valves 100306, 100310, 100312,100313
Defendo Disposable Biopsy, Air/Water and Suction Valves 100314,100315,100316, 100317
DEFENDO Valve and Connector Kit for Olympus GI Endoscopes 100311
DEFENDO biopsy valve 100318,100319,100320
Defendo Olympus Kit 100322, 100323

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 14038-9-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 3 of 3

Endo Carry-on Kit 100800, 100801, 100802, 100803, 100305, 100310
Endoscope Cleaning Brushes and Pull Thru Channel Cleaning Devices 100401, 100402, 100403
Endoscope Cleaning Brushes and Pull Thru Channel Cleaning Devices 100405, 100406
Intercept Beside Kit 100900
Double Balloon Pull Thru SPUP 100414
Micro Pull Thru SPUP 100415
Bite Blocks , Standard Adult 100411
Bite Blocks , Standard Pediatric 100412
EconoTrap 1 Single Chamber Polyp Trap 100101
EconoTrap 2 Double Chamber Polyp Trap 100102
Advantage Polyp Trap Collection Container 100104
AmplifEYE - EYE-101, EYE-102
----------END OF PRODUCT LIST----------

CERTIFICATO CE

Certificato n. 1812/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

CANTEL MEDICAL (ITALY) SRL

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

mantiene nello stabilimento di:

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Lava disinfettatrice-sterilizzatrice chimica a freddo per endoscopi

Sterilizzanti chimici a freddo per dispositivi medici

Disinfettanti per dispositivi medici

Detergente plurienzimatico decontaminante disinfettante per dispositivi medici

Disinfettanti, decontaminanti e detergenti per dispositivi medici

Disinfettanti e detergenti per dispositivi medici

Disinfettanti e decontaminanti per dispositivi medici

Sistemi di conservazione e trasporto di endoscopi

Lava disinfettatrice per endoscopi

serie e modelli indicati in Allegato

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

DM15A0449933-01; DM15E0572628-01; DM16A0607476-01; DM16-0000589; DM16-0002190-01; DM19-0043082-01; DM19-0043104-01; DM20-0050214-01; DM20-0048482-01; DM20-0051086-01; DM20-0047938-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

IMQ

CERTIFICATO CE

Certificato n. 1812/MDD

Allegato

Lava disinfettatrice-sterilizzatrice chimica a freddo per endoscopi
Mod. MEDIVATORS ISA
Marca Cantel Medical (Italy) S.r.l.

Sterilizzanti chimici a freddo per dispositivi medici
Modd. ADASPOR PRONTO; ADASPOR CONCENTRATO, ADASPOR M CONCENTRATO; ADASPOR MONODIE; ADASPOR PENTADIE; ADASPOR SINGLE SHOT; PROLYSTICA AUTO PAA; ISASPOR SINGLE SHOT; ADASPOR PLUS SINGLE SHOT, ADASPOR PLUS PRONTO (READY TO USE); ADASPOR PLUS CONCENTRATO; ADASPOR PLUS MONODIE; ADASPOR PLUS PENTADIE, ADASPOR PLUS M CONCENTRATO.
Marca CANTEL

Disinfettanti per dispositivi medici
Modd. BLUESTERIL ALCOLICO; BLUESTERIL FERRI; BLUESTERIL SPRAY.
Marca CANTEL

Detergente plurienzimatico decontaminante disinfettante per dispositivi medici
Modd. NEO PROTEOZIM PLUS 500; PROTEOZIM PLUS 400.
Marca CANTEL

Disinfettanti, decontaminanti e detergenti per dispositivi medici
Mod. ISACLEAN, PROTEODONT.
Marca CANTEL

Disinfettanti e detergenti per dispositivi medici
Modd. BACTRYL SPRAY; BACTRYL WIPES; ISACLEAN SPRAY; SPOREXIN SPRAY; SPOREXIN WIPES; SPOREXIN VACUUM.
Marca CANTEL

Disinfettanti e decontaminanti per dispositivi medici
Modd. PROTEAZONE; PROTEAZONE OD.
Marca CANTEL

Sistemi di conservazione e trasporto di endoscopi
Modd. CLEANASCOPE; CLEANASCOPE ADVANTAGE.
Marca CANTEL

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Emesso il:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

DocuSign

IMQ

CERTIFICATO CE

Certificato n. 1812/MDD

Allegato

Lava disinfettatrice per endoscopi
Modd. INNOVA E3s; INNOVA E3s CMS; INNOVA E4s CMS.
Marca CANTEL

Emesso il:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

IMQ

EC CERTIFICATE

Certificate No 1812/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

CANTEL MEDICAL (ITALY) SRL

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

manages in the factory of:

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Cold chemical washer disinfector and sterilizer for endoscopes

Cold chemical sterilant for medical devices

Disinfectants for medical devices

Multi-enzyme detergent, decontaminant disinfectant for medical devices

Disinfectants, decontaminants and detergents for medical devices

Disinfectants and detergents for medical devices

Decontaminants and disinfectants for medical devices

Storage and transport systems for endoscopes

Washer disinfector for endoscopes

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM15A0449933-01; DM15E0572628-01; DM16A0607476-01; DM16-0000589; DM16-0002190-01; DM19-0043082-01; DM19-0043104-01; DM20-0050214-01; DM20-0048482-01; DM20-0051086-01; DM20-0047938-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2015-07-20
Updated:	2020-05-08
Substitution Date:	2020-04-07
Expiry Date:	2024-05-26

DocuSign

IMQ

EC CERTIFICATE

Certificate No 1812/MDD

Annex

Cold chemical washer disinfector and sterilizer for endoscopes
Type ref. MEDIVATORS ISA
Trade mark Cantel Medical (Italy) S.r.l.

Cold chemical sterilant for medical devices
Type ref. ADASPOR PRONTO; ADASPOR CONCENTRATO, ADASPOR M CONCENTRATO; ADASPOR MONODIE; ADASPOR PENTADIE; ADASPOR SINGLE SHOT; PROLYSTICA AUTO PAA; ISASPOR SINGLE SHOT; ADASPOR PLUS SINGLE SHOT, ADASPOR PLUS PRONTO (READY TO USE); ADASPOR PLUS CONCENTRATO; ADASPOR PLUS MONODIE; ADASPOR PLUS PENTADIE, ADASPOR PLUS M CONCENTRATO.
Trade mark CANTEL

Disinfectants for medical devices
Type ref. BLUESTERIL ALCOLICO; BLUESTERIL FERRI; BLUESTERIL SPRAY.
Trade mark CANTEL

Multi-enzyme detergent, decontaminant disinfectant for medical devices
Type ref. NEO PROTEOZIM PLUS 500; PROTEOZIM PLUS 400.
Trade mark CANTEL

Disinfectants, decontaminants and detergents for medical devices
Type ref. ISACLEAN, PROTEODONT.
Trade mark CANTEL

Disinfectants and detergents for medical devices
Type ref. BACTRYL SPRAY; BACTRYL WIPES; ISACLEAN SPRAY; SPOREXIN SPRAY; SPOREXIN WIPES; SPOREXIN VACUUM.
Trade mark CANTEL

Decontaminants and disinfectants for medical devices
Type ref. PROTEAZONE; PROTEAZONE OD.
Trade mark CANTEL

Storage and transport systems for endoscopes
Type ref. CLEANASCOPE; CLEANASCOPE ADVANTAGE.
Trade mark CANTEL

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Date: 2015-07-20
Updated: 2020-05-08
Substitution Date: 2020-04-07
Expiry Date: 2024-05-26

IMQ

This is a translation of the Italian text, which prevails in case of doubts

EC CERTIFICATE

Certificate No 1812/MDD

Annex

Washer disinfector for endoscopes

Type ref. INNOVA E3s; INNOVA E3s CMS; INNOVA E4s CMS.
Trade mark CANTEL

Date:	2015-07-20
Updated:	2020-05-08
Substitution Date:	2020-04-07
Expiry Date:	2024-05-26

IMQ

This is a translation of the Italian text, which prevails in case of doubts

DICHIARAZIONE DI CONFORMITA CE
EC DECLARATION OF CONFORMITY

Nome del Fabbricante Manufacturer's Name	**CANTEL MEDICAL (ITALY) S.R.L.**
Indirizzo del Fabbricante Manufacturer's address	Via Laurentina, 169 – 00071 Pomezia (Roma) - Italy
Nome del Dispositivo Medico Name of the Medical Device	**MEDIVATORS ISA**
Codice Identificativo Identification code	**ISA/CE/007**
Classe del prodotto Device Class	**IIb**
Destinazione d'uso Fields covered	Lava-Disinfettatrice chimica a freddo per endoscopi. Cold chemical Wash Disinfector for endoscopes
Sistema di Qualità Quality System	**UNI EN ISO 9001 – UNI EN ISO 13485**
Organismo Notificato Notified Body	IMQ S.P.A.– via Quintiliano,43 – 20138 Milano – Italy
Numero Certificato CE CE Certificate No.	1812/MDD

La sottoscritta CANTEL MEDICAL (ITALY) S.R.L. , dichiara che il dispositivo Medico **MEDIVATORS ISA** è conforme ai requisiti dell' Allegato II della Direttiva 93/42/CEE e s.m.i. e risponde ai requisiti essenziali della direttiva suddetta ad esso applicabili, in tutte le fasi dalla progettazione al controllo finale.
La CANTEL MEDICAL (ITALY) S.R.L. dichiara, inoltre, che il prodotto è conforme alle seguenti normative:

UNI EN ISO 15883-1
UNI EN ISO 15883-4
UNI CEN ISO/TS 15883-5
IEC 61010-1
IEC 61010-2-040
EN 61326-1
CEI EN 62366

The undersigned CANTEL MEDICAL (ITALY) S.R.L.. declares that the medical device **MEDIVATORS ISA** meets the requirements of Annex II of EEC Directive 93/42 and its revised version and meets the applicable provisions thereof with the relevant essential requirements of the aforementioned directive from design to final inspection and testing.
CANTEL MEDICAL (ITALY) S.R.L. also claims that the product meets the following standards:

UNI EN ISO 15883-1
UNI EN ISO 15883-4
UNI CEN ISO/TS 15883-5
IEC 61010-1
IEC 61010-2-040
EN 61326-1
CEI EN 62366

MANAGING DIRECTOR

Data/date 11/09/2017 V. M. SUPEKAR

GIORNO/DAY - MESE/MONTH - ANNO/YEAR

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Medivators Inc.
3150 Pollok Dr.
Conroe, TX 77303
USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design and Development, Manufacture, and Distribution of Medical Devces used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile Tubing Sets, Endoscopy Cuffs, Endoscopy Procedure Kits, and related accessories.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4716)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices
/ Head of Notified Body

Registration Number: MD19.4716
Certification Granted: May 30, 2012
Effective Date: June 02, 2020
Expiry Date: May 15, 2022

Annex to Certificate Number: MD19.4716

Scope of Registration:

The Design and Development, Manufacture, and Distribution of Medical Devces used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile Tubing Sets, Endoscopy Cuffs, Endoscopy Procedure Kits, and related accessories.

Activity	Location
HQ, Administration, Design & Development, Manufacturing, Distribution	Medivators Inc. 3150 Pollok Dr. Conroe, TX 77303 USA File No.: MD19.4716
Design & Development	Medivators Inc. 3101 Pollok Dr. Conroe, TX 77303 USA File No.: MD19.4716/A
Administration, Manufacturing	Medivators Inc. 501 North Farm to Market 3083 Rd E Conroe, TX 77303 USA File No.: MD19.4716/B
Manufacturing, Distribution	Medivators Inc. 750 Conroe Park North Conroe, TX 77303 USA File No: MD19.4716/C

Annex to Certificate Number: MD19.4716

Scope of Registration:

The Design and Development, Manufacture, and Distribution of Medical Devces used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile Tubing Sets, Endoscopy Cuffs, Endoscopy Procedure Kits, and related accessories.

Activity	Location
Distribution	Medivators Inc. 3155 Conroe Park North Conroe, TX 77303 USA File No: MD19.4716/D

Verified by:
Operations Manager